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### A Study of Ixekizumab (LY2439821) in TNF Inhibitor Experienced Participants With Radiographic Axial Spondyloarthritis (COAST-W)

ClinicalTrials.gov ID ⓘ NCT02696798

Sponsor ⓘ Eli Lilly and Company

Information provided by ⓘ Eli Lilly and Company (Responsible Party)

Last Update Posted ⓘ 2020-06-17

Completed ⓘ

No longer looking for participants

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#### Study Overview

##### Brief Summary

The main purpose of this study is to evaluate the efficacy and safety of ixekizumab in tumor necrosis factor (TNF) inhibitor-experienced participants with radiographic axial spondyloarthritis (rad-axSpA).

##### Official Title

A Multicenter, Randomized, Double-Blind, Placebo- Controlled 16-Week Study Followed by Long-Term Evaluation of Efficacy and Safety of Ixekizumab (LY2439821) in TNFi-Experienced Patients With Radiographic Axial Spondyloarthritis

##### Conditions ⓘ

Spondyloarthritis

##### Intervention/Treatment ⓘ

- Drug: Ixekizumab
- Drug: Placebo

##### Other Study ID Numbers ⓘ

- 16179
- I1F-MC-RHBW ( Other Identifier ) (OTHER: Eli Lilly and Company)
- 2015-003937-84 ( EudraCT Number )

##### Study Start (Actual) ⓘ

2016-04-12

##### Primary Completion (Actual) ⓘ

2018-05-18

##### Study Completion (Actual) ⓘ

2019-05-03

##### Enrollment (Actual) ⓘ

316

##### Study Type ⓘ

Interventional

##### Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine



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- 11F-MC-RHBW ( Other Identifier ) (OTHER: Eli Lilly and Company)
- 2015-003937-84 ( EudraCT Number )

## Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](#) related topics: [Ankylosing spondylitis](#)

[MedlinePlus](#) related topics: [Ankylosing Spondylitis](#)

[Drug Information](#) available for: [Ixekizumab](#)

[FDA Drug and Device Resources](#)

## Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#).

This study has 99 locations

### United States

#### Arizona Locations

- Phoenix, Arizona, United States, 85032  
Arizona Arthritis Research, PLC

#### California Locations

- Escondido, California, United States, 92025  
Rheumatology Center of San Diego
- Huntington Beach, California, United States, 92648  
Care Access Research - Huntington Beach
- Palm Desert, California, United States, 92260  
Desert Medical Advances

#### Colorado Locations

- Colorado Springs, Colorado, United States, 80920  
Arthritis Assoc. & Osteoporosis Ctr of Colorado Springs, LLC
- Denver, Colorado, United States, 80230  
Denver Arthritis Center

#### Connecticut Locations

- Danbury, Connecticut, United States, 06810  
Clinical Research Center of CT/NY

#### Florida Locations

- Aventura, Florida, United States, 33180  
Arthritis Rheumatic Disease Specialties
- Sarasota, Florida, United States, 34239  
Sarasota Arthritis Center

#### Georgia Locations

- Marietta, Georgia, United States, 30060  
Marietta Rheumatology

#### Idaho Locations

- Boise, Idaho, United States, 83702  
St Luke's Clinic - Intermountain Orthopaedics
- Idaho Falls, Idaho, United States, 83404  
Institute of Arthritis Research

#### Kentucky Locations

- Elizabethtown, Kentucky, United States, 42701  
Center for Arthritis & Osteoporosis

#### Maryland Locations

- Cumberland, Maryland, United States, 21502  
Klein and Associates MD, PA



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This study has 99 locations

**Kentucky Locations**

**Elizabethtown, Kentucky, United States, 42701**  
Center for Arthritis & Osteoporosis

**Maryland Locations**

**Cumberland, Maryland, United States, 21502**  
Klein and Associates MD, PA

**Hagerstown, Maryland, United States, 21740**  
Osteoporosis And Clinical Trial Center

**Missouri Locations**

**St Louis, Missouri, United States, 63141**  
Arthritis Consultants

**New York Locations**

**Albany, New York, United States, 12203**  
The Center for Rheumatology

**North Carolina Locations**

**Raleigh, North Carolina, United States, 27617**  
Shanahan Rheumatology & Immunotherapy

**Oregon Locations**

**Portland, Oregon, United States, 97239**  
Oregon Health and Science University

**Pennsylvania Locations**

**Duncansville, Pennsylvania, United States, 16635**  
Altoona Center for Clinical Research

**South Carolina Locations**

**Columbia, South Carolina, United States, 29204**  
Articularis Healthcare Group, INC dba Columbia Arthritis Ctr

**North Charleston, South Carolina, United States, 29406**  
Low Country Research Center

**Texas Locations**

**Houston, Texas, United States, 77030**  
Univ of Texas Health Science Center - Houston

**Mesquite, Texas, United States, 75150**  
Southwest Rheumatology, P.A.

**Virginia Locations**

**Chesapeake, Virginia, United States, 23320**  
Center for Arthritis and Rheumatic Diseases, PC

**Washington Locations**

**Spokane, Washington, United States, 99204**  
Arthritis Northwest Rheumatology

**Wisconsin Locations**

**Franklin, Wisconsin, United States, 53132**  
Rheumatology and Immunotherapy Center

**Argentina**

**Rosario, Argentina, S2000CFJ**  
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Rosario, Argentina, S2000DEJ**  
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**San Miguel de Tucumán, Argentina, T4000AXL**  
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**San Miguel de Tucumán, Argentina, T4000BRD**  
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Brazil**

**Curitiba, Brazil, 80440-080**  
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Goiás, Brazil, 74043-110**

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## Brazil

### Curitiba, Brazil, 80440-080

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Goiás, Brazil, 74043-110

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Juiz de Fora, Brazil, 36010-570

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Porto Alegre, Brazil, 90480-000

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### São Paulo, Brazil, 01244-030

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

## Canada

### St. John's, Canada, A1C 5B8

For additional information regarding investigative sites for this trial, contact 1-888-545-5972 Mon - Fri, 9 AM to 4 PM or 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri, 9 AM to 5 PM Eastern Time or speak with your personal physician.

### Trois-Rivières, Canada, G8Z 1Y2

For additional information regarding investigative sites for this trial, contact 1-888-545-5972 Mon - Fri, 9 AM to 4 PM or 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri, 9 AM to 5 PM Eastern Time or speak with your personal physician.

### Victoria, Canada, V8V 3M9

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

## Finland

### Helsinki, Finland, 00029

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Hyvinkää, Finland, 05800

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Oulu, Finland, 90029

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

## France

### Clermont, France, 63003

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Le Kremlin-Bicêtre, France, 94270

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Montpellier, France, 34295

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Orléans, France, 45100

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### Paris, France, 75679

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.



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[Paris, France, 75679](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Tours, France, 37044](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Germany](#)[Berlin, Germany, 10117](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Israel](#)[Ashkelon, Israel, 7830604](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Haifa, Israel, 3525408](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Petah Tikva, Israel, 4941492](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Tel Aviv, Israel, 6423906](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Italy](#)[Milan, Italy, 20157](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Reggio Emilia, Italy, 42123](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Roma, Italy, 00168](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Siena, Italy, 53100](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Japan](#)[Hyōgo, Japan, 663-8501](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Yamagata, Japan, 990-9585](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Mexico](#)[Chihuahua City, Mexico, 31000](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Guadalajara, Mexico, 44650](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Mexicali, Mexico, 21200](#)[Click to view interactive map](#)

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[Guadalajara, Mexico, 44650](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Mexicali, Mexico, 21200](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Mérida, Mexico, 97070](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Monterrey, Mexico, 64020](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[San Luis Potosí City, Mexico, 78213](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

## Netherlands

[Amsterdam, Netherlands, 1105 AZ](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Sneek, Netherlands, 8601 ZK](#)

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## Poland

[Bydgoszcz, Poland, 85-168](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Elblag, Poland, 82-300](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Lodz, Poland, 90-558](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Poznan, Poland, 61-397](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Świdnik, Poland, 21-040](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Warsaw, Poland, 01-518](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Warsaw, Poland, 02-691](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

## Puerto Rico

[Santurce, Puerto Rico, 00909](#)

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

### PR Locations

[Caguas, PR, Puerto Rico, 00725](#)

Office: Perez-De Jesus, Amarillis

[San Juan, PR, Puerto Rico, 00909](#)

GCM Medical Group PSC

[San Juan, PR, Puerto Rico, 00909](#)

GCM Medical Group PSC





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**Seville, Spain, 41010**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**United Kingdom****Basingstoke, United Kingdom, RG24 9NA**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Norwich, United Kingdom, NR4 7UY**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Solihull, United Kingdom, B91 3JL**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Stoke-on-Trent, United Kingdom, ST6 7AG**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Wolverhampton, United Kingdom, WV10 0QP**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

**Wythenshawe, United Kingdom, M23 9LT**

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST), or speak with your personal physician.

[Click to view interactive map](#)**Participation Criteria**

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#).

**Eligibility Criteria**

## Description

## Inclusion Criteria:

- Are ambulatory.
- Have an established diagnosis of radiographic axial spondyloarthritis (rad-xSpA) with sacroiliitis defined radiographically according to the modified New York criteria.
- Participants have a history of back pain  $\geq 3$  months with age at onset  $< 45$  years.
- Have had prior treatment with at least 1 and not more than 2 TNF inhibitors.
- Must have had an inadequate response to 2 or more NSAIDs at the therapeutic dose range for a total duration of at least 4 weeks OR have a history of intolerance to NSAIDs.
- Have a history of prior therapy for axSpa for at least 12 weeks prior to screening.

## Exclusion Criteria:

- Have total ankylosis of the spine.
- Have never taken a TNF inhibitor medication or have taken more than 2.
- Have recently received a live vaccine within 12 weeks or have had a vaccination with Bacillus Calmette-Guerin (BCG) within the past year.
- Have an ongoing or serious infection within the last 12 weeks or evidence of active tuberculosis.
- Have a compromised immune system.
- Have any other serious and/or uncontrolled diseases.
- Have either a current diagnosis or a recent history of malignant disease.
- Have had major surgery within 8 weeks of baseline, or will require surgery during the

## Ages Eligible for Study

18 Years and older (Adult, Older Adult )

## Sexes Eligible for Study

All

## Accepts Healthy Volunteers

No

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Bacillus Calmette-Guérin (BCG) within the past year.

- Have an ongoing or serious infection within the last 12 weeks or evidence of active tuberculosis.
- Have a compromised immune system.
- Have any other serious and/or uncontrolled diseases.
- Have either a current diagnosis or a recent history of malignant disease.
- Have had major surgery within 8 weeks of baseline, or will require surgery during the study.
- Are pregnant or breastfeeding.

## Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

[Expand all](#) / [Collapse all](#)

### How is the study designed?

#### Design Details

**Primary Purpose** ⓘ : Treatment

**Allocation** ⓘ : Randomized

**Interventional Model** ⓘ : Parallel Assignment

**Masking** ⓘ : Double (Participant, Investigator)

#### Arms and Interventions

| Participant Group/Arm ⓘ                                                                                                                                                                                                                                                                                               | Intervention/Treatment ⓘ                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Experimental: Q2W Ixekizumab<br><br>Double Blind Period: Starting dose of 80 or 160 milligrams (mg) ixekizumab given subcutaneously (SC) at baseline followed by 80 mg ixekizumab given SC every two weeks (Q2W) to week 14.<br><br>Extended Treatment Period: 80 mg ixekizumab given SC Q2W from week 16 to week 52. | Drug: Ixekizumab <ul style="list-style-type: none"><li>• Administered SC</li><li>• Other Names:<ul style="list-style-type: none"><li>◦ LY2439821</li></ul></li></ul>                                                                                 |
| Experimental: Q4W Ixekizumab<br><br>Double Blind Period: Starting dose of 80 or 160 mg ixekizumab given SC at baseline followed by 80 mg ixekizumab given SC every four weeks (Q4W) to week 14.<br><br>Extended Treatment Period: 80 mg ixekizumab given SC Q4W from week 16 to week 52.                              | Drug: Ixekizumab <ul style="list-style-type: none"><li>• Administered SC</li><li>• Other Names:<ul style="list-style-type: none"><li>◦ LY2439821</li></ul></li></ul>                                                                                 |
| Placebo Comparator: Placebo<br><br>Double Blind Period: Placebo given SC Q2W to week 14.<br><br>Extended Treatment Period: Starting dose of 160 mg ixekizumab given SC at week 16 followed by 80 mg ixekizumab                                                                                                        | Drug: Ixekizumab <ul style="list-style-type: none"><li>• Administered SC</li><li>• Other Names:<ul style="list-style-type: none"><li>◦ LY2439821</li></ul></li></ul> Drug: Placebo <ul style="list-style-type: none"><li>• Administered SC</li></ul> |

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Double Blind Period: Placebo given SC Q2W to week 14.

Extended Treatment Period: Starting dose of 160 mg ixekizumab given SC at week 16 followed by 80 mg ixekizumab given SC Q2W or Q4W from week 16 to week 52.

- Administered SC

- Other Names:
  - LY2439821

Drug: Placebo

- Administered SC

## What is the study measuring?

### Primary Outcome Measures

| Outcome Measure                                                                                                    | Measure Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Time Frame |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Percentage of Participants Achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) Response | <p>ASAS40 is defined as improvement from baseline of greater than or equal to (<math>\geq</math>) 40 % and absolute improvement from baseline of at least 2 units (range of 0 to 10) in at least 3 of the following 4 domains without any worsening in the remaining domain.</p> <ol style="list-style-type: none"><li>1. Patient Global: How active was your spondylitis on average during the last week? score ranges 0 (not active) to 10 (very active).</li><li>2. Spinal Pain: How much Pain of your spine due to Ankylosing spondylitis? score ranges 0 (no pain) to 10 (severe pain).</li><li>3. Bath Ankylosing Spondylitis Functional Index (BASFI): Participant asked to rate the difficulty associated with 10 individual basic functional activities. Participant response was captured using Numeric Rating Scale (NRS) (range 0 to 10) with a higher score indicating worse function.</li><li>4. Inflammation based on Q5 &amp; Q6 mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (mean of intensity &amp; duration of stiffness): Score ranges from "0" (none) and "10" (very severe).</li></ol> | Week 16    |

### Secondary Outcome Measures

| Outcome Measure                                         | Measure Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Time Frame        |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Percentage of Participants Achieving an ASAS20 Response | <p>ASAS20 response is defined as a <math>\geq</math>20% improvement and an absolute improvement from baseline of <math>\geq</math>1 units (range 0 to 10) in <math>\geq</math>3 of 4 domains, and no worsening of <math>\geq</math>20% and <math>\geq</math>1 unit (range 0 to 10) in the remaining domain.</p> <ol style="list-style-type: none"><li>1. Patient Global: How active was your spondylitis on average during the last week? score ranges 0 (not active) to 10 (very active).</li><li>2. Spinal Pain: How much Pain of your spine due to Ankylosing spondylitis? score ranges 0 (no pain) to 10 (severe pain).</li><li>3. Bath Ankylosing Spondylitis Functional Index (BASFI): Participant asked to rate the difficulty associated with 10 individual basic functional activities. Participant response was captured using Numeric Rating Scale (NRS) (range 0 to 10) with a higher score indicating worse function.</li><li>4. Inflammation based on Q5 &amp; Q6 mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (mean of intensity &amp; duration of stiffness): Score ranges from "0" (none) and "10" (very severe).</li></ol> | Week 16           |
| Change From Baseline in Ankylosing Spondylitis          | <p>ASDAS is a composite index to assess disease activity in AS. The parameters used for the ASDAS (with CRP as acute phase reactant) are</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Baseline, Week 16 |

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|----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
|                                                                                                                | 4. Inflammation based on Q5 & Q6 mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (mean of intensity & duration of stiffness): Score ranges from "0" (none) and "10" (very severe).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                   |
| Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)                                  | <p>ASDAS is a composite index to assess disease activity in AS. The parameters used for the ASDAS (with CRP as acute phase reactant) are</p> <ol style="list-style-type: none"> <li>1. Total back pain</li> <li>2. Patient global</li> <li>3. Peripheral pain/swelling</li> <li>4. Duration of morning stiffness and</li> <li>5. CRP in mg/L. The ASDAScrp is calculated with the following equation: <math>0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \ln(\text{CRP} + 1)</math>. (CRP is in mg/liter, the range of other variables is from 0 (normal) to 10 (very severe); Ln represents the natural logarithm). Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher scores indicated higher disease activity. Least Square (LS) mean was determined by mixed-model repeated measures (MMRM) with treatment, geographic region, baseline CRP status, number of prior tumor necrosis factor inhibitor (TNFi), baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.</li> </ol> | Baseline, Week 16 |
| Percentage of Participants Achieving Bath Ankylosing Spondylitis Disease Activity Index 50 (BASDAI50) Response | The BASDAI is a participant-reported assessment consisting of 6 questions that relate to 5 major symptoms relevant to radiographic axial spondyloarthritis (rad-axSpA): 1) Fatigue, 2) Spinal pain, 3) Peripheral arthritis, 4) Enthesitis, 5) Intensity, and 6) Duration of morning stiffness. Participants need to score each item with a score from 0 to 10 (NRS). Total score is obtained from the average of symptom scores ranging 0 (no problem) to 10 (worst problem), with a higher score indicating more severe AS symptom. BASDAI50 represents an improvement of $\geq 50\%$ of the BASDAI score from baseline.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Week 16           |
| Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)                            | The BASDAI is a participant-reported assessment consisting of 6 questions that relate to 5 major symptoms relevant to radiographic axial spondyloarthritis (rad-axSpA): 1) Fatigue, 2) Spinal pain, 3) Peripheral arthritis, 4) Enthesitis, 5) Intensity, and 6) Duration of morning stiffness. Participants need to score each item with a score from 0 to 10 (NRS). Total score is obtained from the average of symptom scores ranging 0 (no problem) to 10 (worst problem), with a higher score indicating more severe AS symptom. LSmean was determined by MMRM with factors for treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Baseline, Week 16 |
| Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI)                                   | The BASFI is a participant-reported assessment that establishes a participant's functional baseline and subsequent response to treatment. The BASFI is composed with 10 questions to assess the disease severity, including the first 8 questions regarding to functional anatomy related activities and the remaining 2 questions related to daily activities of AS participants. Participants respond to each question using an NRS scale (range 0 to 10). The BASFI score is the average of the 10 responses and has a possible minimum value of 0 and a possible maximum value of 10, with a higher score indicating worse function. LS mean was determined by MMRM with factors for treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                         | Baseline, Week 16 |
| Percentage of Participants Achieving ASDAS Inactive                                                            | ASDAS is a composite index to assess disease activity in AS. ASDAS Inactive Disease is defined as a score of $< 1.3$ .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Week 16           |

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|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
|                                                                                                                                             | with factors for treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                   |
| Percentage of Participants Achieving ASDAS Inactive Disease                                                                                 | <p>ASDAS is a composite index to assess disease activity in AS. ASDAS Inactive Disease is defined as a score of &lt;1.3.</p> <p>The parameters used for the ASDAS (with CRP as acute phase reactant) are</p> <ol style="list-style-type: none"> <li>1. Total back pain</li> <li>2. Patient global</li> <li>3. Peripheral pain/swelling</li> <li>4. Duration of morning stiffness and</li> <li>5. CRP in mg/L. The ASDAScrp is calculated with the following equation: <math>0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \ln(\text{CRP} + 1)</math>. (CRP is in mg/liter, the range of other variables is from 0 (normal) to 10 (very severe); Ln represents the natural logarithm). Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher the score worse the disease activity.</li> </ol> | Week 16           |
| Percentage of Participants Achieving ASDAS <2.1                                                                                             | <p>ASDAS is a composite index to assess disease activity in AS. ASDAS &lt;2.1 defines moderate disease activity.</p> <p>The parameters used for the ASDAS (with CRP as acute phase reactant) are</p> <ol style="list-style-type: none"> <li>1. Total back pain</li> <li>2. Patient global</li> <li>3. Peripheral pain/swelling</li> <li>4. Duration of morning stiffness and</li> <li>5. CRP in mg/L. The ASDAScrp is calculated with the following equation: <math>0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \ln(\text{CRP} + 1)</math>. (CRP is in mg/liter, the range of other variables is from 0 (normal) to 10 (very severe); Ln represents the natural logarithm). Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher the score worse the disease activity.</li> </ol>         | Week 16           |
| Change From Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores | The SF-36 is a 36-item participant administered measure designed to be a short, multipurpose assessment of health in the areas of physical functioning, role - physical, role - emotional, bodily pain, vitality, social functioning, mental health, and general health. The 2 overarching domains of mental well-being and physical well-being are captured by the Mental Component Summary and Physical Component Summary scores. T-scores are used for analysis. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. LSmean was determined by MMRM with factors for treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                  | Baseline, Week 16 |
| Change From Baseline in ASAS Health Index (ASAS HI)                                                                                         | The ASAS Health Index (ASAS HI) is a disease specific health-index instrument designed to assess the impact of interventions for SpA, including axSpA. The 17 item instrument has scores ranging from 0 (good Health) to 17 (poor Health). Each item consists of 1 question that the patient needs to respond to with either "I agree" (score 1) or "I do not agree" (score 0)." A score of "1" is given where the item is affirmed, indicating adverse health. All item scores are summed to give a total score or index. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                            | Baseline, Week 16 |
| Change From Baseline in                                                                                                                     | The study used MRI with fat-saturating techniques such as short tau                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Baseline, Week    |

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|                                                                                                                                                            | (score 0). A score of 1 is given where the item is affirmed, indicating adverse health. All item scores are summed to give a total score or index. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
| Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Ankylosing Spondylitis Spinal Magnetic Resonance Imaging [ASSpiMRI] - Berlin Score) | The study used MRI with fat-saturating techniques such as short tau inversion recovery (STIR) to look for the presence of bone marrow edema. The Berlin modification of Ankylosing Spondylitis spine MRI score for activity (ASSpiMRI) scoring technique assesses inflammation in each of the 23 disco-vertebral units (DVU) of the spine (from C2 to S1), capturing bone marrow edema. Scores for each DVU range from 0-3 (0=normal; 1=minor bone marrow edema [less than or equal to 25% of DVU]; 3=severe bone marrow edema (more than 50% of DVU)). The composite score ranges from 0 to 69, with higher scores reflecting worse disease. LS mean was determined by analysis of covariance (ANCOVA) with treatment, geographic region, baseline CRP status, number of prior TNF inhibitors used and baseline value as fixed factors. | Baseline, Week 16 |
| Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score)                     | MRI score of spine was assessed using SPARCC method. All 23 disco-vertebral units (DVU) of the spine (from C2 to S1) were scored for bone marrow edema. A single DVU has 18 scoring units, and each has score of 0 or 1, bringing the maximum total score to 414, the sum ranges from 0 to 414 with higher scores reflecting worse disease. Scoring was performed by central readers. LS mean was determined by ANCOVA with factors for treatment, geographic region, baseline CRP status, number of prior TNF inhibitors used and baseline value.                                                                                                                                                                                                                                                                                       | Baseline, Week 16 |
| Change From Baseline in the Measure of High Sensitivity C-Reactive Protein (CRP)                                                                           | High sensitivity CRP is the measure of acute phase reactant. It was measured with a high sensitivity assay at the central laboratory to help assess the effect of ixekizumab on disease activity. High sensitivity CRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                            | Baseline, Week 16 |
| Change From Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI)                                                                                | BASMI is a combined index comprising of 5 clinical measurements of spinal mobility in patients with radiographic axial spondyloarthritis (rad-axSpA). <ol style="list-style-type: none"> <li>1. Lateral Spinal Flexion</li> <li>2. Tragus-to-wall distance</li> <li>3. Lumbar Flexion (modified Schober)</li> <li>4. Maximal intermalleolar distance and</li> <li>5. Cervical rotation. The BASMI linear result is the average of the 5 assessments and ranges from 0 to 10. The higher the BASMI score the more severe the patient's limitation of movement due to their AS.</li> </ol> LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit and treatment-by-visit interaction as fixed factors.                                | Baseline, Week 16 |
| Change From Baseline in Chest Expansion                                                                                                                    | Chest expansion is the difference, in centimeter (cm), between the circumference of the chest in maximal inspiration and maximal expiration. While patients have their hands resting on or behind the head, the assessor will measure the chest encircled length by centimeter (cm) at the fourth intercostal level anteriorly. Two tries were recorded. The better measurement (larger difference) of 2 tries (in centimeters) was used for analyses. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit and treatment-by-visit interaction as fixed factors.                                                                                                                                                                  | Baseline, Week 16 |
| Change From Baseline in                                                                                                                                    | The participant is to make a maximum effort to touch the head against the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Baseline, Week    |

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|                                                                                                   | measurement (larger difference) of 2 tries (in centimeters) was used for analyses. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                   |
| Change From Baseline in Occiput to Wall Distance                                                  | The participant is to make a maximum effort to touch the head against the wall when standing with heels and back against the wall (occiput). Then the distance from occiput to wall is measured. Two tries will be recorded. The better (smaller) measurement of 2 tries (in centimeters) will be used for analyses. LS mean was determined by MMRM with factors for treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                                                    | Baseline, Week 16 |
| Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES)                | The MASES is an index used to measure the severity of enthesitis. The MASES assesses 13 sites for enthesitis using a score of "0" for no activity or "1" for activity. Sites assessed include costochondral 1 (right/left), costochondral 7 (right/left), spinal iliaca anterior superior (right/left), crista iliaca (right/left), spina iliaca posterior (right/left), processus spinosus L5, and Achilles tendon proximal insertion (right/left). The MASES is the sum of all site scores (range 0 to 13); higher scores indicate more severe enthesitis. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                       | Baseline, Week 16 |
| Change From Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Score | The SPARCC enthesitis is an index used to measure the severity of enthesitis. The SPARCC assesses 16 sites for enthesitis using a score of "0" for no activity or "1" for activity. Sites assessed include Medial epicondyle (left/right [L/R]), Lateral epicondyle (L/R), Supraspinatus insertion into greater tuberosity of humerus (L/R), Greater trochanter (L/R), Quadriceps insertion into superior border of patella (L/R), Patellar ligament insertion into inferior pole of patella or tibial tubercle (L/R), Achilles tendon insertion into calcaneum (L/R), and Plantar fascia insertion into calcaneum (L/R). The SPARCC is the sum of all site scores (range 0 to 16). Higher scores indicate more severe enthesitis. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors. | Baseline, Week 16 |
| Change From Baseline in Severity of Peripheral Arthritis by Tender Joint Count (TJC) Scores       | The number of tender and painful joints was determined by examination of 46 joints (23 joints on each side of the body). The 46 joints were assessed and classified as tender or not tender. Sum of all joints checked to be tender/painful divided by number of evaluable joints which was multiplied by 46 to obtain TJC score. The scores ranges from 0 (no tender/painful joints) to 46 (all joints tender/painful). LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction.                                                                                                                                                                                                                                                                                                                            | Baseline, Week 16 |
| Change From Baseline in Severity of Peripheral Arthritis by Swollen Joint Count (SJC) Scores      | The number of swollen joints was determined by examination of 44 joints (22 joints on each side of the body). The 44 joints were assessed and classified as swollen or not swollen. Sum of all joints checked to be swollen divided by number of evaluable joints which was multiplied by 44 to obtain SJC score. The SJC score ranges from 0 (no swollen joints) to 44 (all joints swollen). LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction.                                                                                                                                                                                                                                                                                                                                                       | Baseline, Week 16 |
| Percentage of Participants With Anterior Uveitis                                                  | Anterior uveitis is an inflammation of the middle layer of the eye. which includes the iris (colored part of the eye) and the adjacent tissue, known as the ciliary body.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Week 16           |
|                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                   |

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|                                                                                                       | baseline value-by-visit, and treatment-by-visit interaction.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |
| Percentage of Participants With Anterior Uveitis                                                      | Anterior uveitis is an inflammation of the middle layer of the eye, which includes the iris (colored part of the eye) and the adjacent tissue, known as the ciliary body.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Week 16           |
| Change From Baseline in the Fatigue Numeric Rating Scale (NRS) Score                                  | The fatigue severity NRS is a participant administered single-item 11-point horizontal scale anchored at 0 and 10, with 0 representing "no fatigue" and 10 representing "as bad as you can imagine". Participants rate their fatigue (feeling tired or worn out) by circling the 1 number that describes their worst level of fatigue during the previous 24 hours. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.                                                                                                                                                                                                                                                                                                                                                                    | Baseline, Week 16 |
| Change From Baseline in the Jenkins Sleep Evaluation Questionnaire (JSEQ)                             | The Jenkins Sleep Evaluation Questionnaire (JSEQ) is a 4 item scale designed to estimate sleep problems in clinical research. The JSEQ assesses the frequency of sleep disturbance in 4 categories: 1) trouble falling asleep, 2) waking up several times during the night, 3) having trouble staying asleep (including waking up far too early), and 4) waking up after the usual amount of sleep feeling tired and worn out. Patients report the numbers of days they experience each of these problems in the past month on a 6 point Likert Scale ranging from 0 = "no days" to 5 = "22-30 days". The total JSEQ score ranges from 0 to 20, with higher scores indicating greater sleep disturbance. LS mean was determined by MMRM with treatment, geographic region, baseline CRP status, number of prior TNFi, baseline value, visit, baseline value-by-visit and treatment-by-visit interaction as fixed factors.                                | Baseline, Week 16 |
| Change From Baseline in the Work Productivity Activity Impairment Spondyloarthritis (WPAI-SpA) Scores | The WPAI-SpA consists of 6 questions to determine employment status, hours missed from work because of SpA, hours missed from work for other reasons, hours actually worked, the degree to which SpA affected work productivity while at work, and the degree to which SpA affected activities outside of work. The WPAI-SpA has been validated in the rad-axSpA patient population. Four scores are derived: percentage of absenteeism, percentage of presenteeism (reduced productivity while at work), an overall work impairment score that combines absenteeism and presenteeism, and percentage of impairment in activities performed outside of work. The computed percentage range for each sub-scale was from 0-100, with higher scores indicating greater impairment and less productivity. LS mean was determined by ANCOVA with treatment, geographic region, baseline CRP status, number of prior TNFi and baseline value as fixed factors. | Baseline, Week 16 |
| Change From Baseline in ASAS-Nonsteroidal Anti-Inflammatory Drug (NSAID) Score                        | ASAS-NSAID score is used to present the NSAID intake by considering the type of NSAID, the total dose, & the number of days taking NSAID during a period of interest (PI). For NSAID equivalent scoring system, range is from 0 to 100, higher the score greater the NSAID intake. ASAS-NSAID score= (equivalent NSAID score) x (days of intake during PI) x (days per week)/(PI in days).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Baseline, Week 52 |
| Percentage of Participants With Anti-Ixekizumab Antibodies                                            | A treatment emergent - antidrug antibody (TE-ADA) positive patient is defined as: a) a patient with a $\geq 4$ -fold increase over a positive baseline antibody titer; or b) for a negative baseline titer, a patient with an increase from the baseline to a level of $\geq 1:10$ . Percentage was calculated based on the number of evaluable participants and was calculated by number of participants with treatment-emergent positive anti-ixekizumab antibodies / number of evaluable participants * 100%.                                                                                                                                                                                                                                                                                                                                                                                                                                         | Week 16           |
| Pharmacokinetics (PK): Trough Ixekizumab Concentration at Steady State (C <sub>trough ss</sub> )      | Pharmacokinetics (PK): Steady-state trough serum concentration of Ixekizumab at week 16.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Week 16           |

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number of evaluable participants \* 100%.

Pharmacokinetics (PK):  
Trough Ixekizumab  
Concentration at Steady  
State (Ctrough ss)Pharmacokinetics (PK): Steady-state trough serum concentration of  
Ixekizumab at week 16.

Week 16

## Collaborators and Investigators

This is where you will find people and organizations involved with this study.

### Sponsor

**Eli Lilly and Company**

### Investigators

- Study Director: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST), Eli Lilly and Company

## Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- [Reveille JD, Rudwaleit M, Rahman P, Maldonado-Cocco JA, Magrey M, Bolce R, Ng KJ, Gible TH, Lisse J, Park SY, Kronbergs A, Navarro-Compan V. Does HLA-B27 Status Influence Ixekizumab Efficacy in Axial Spondyloarthritis? Results From the COAST-V, COAST-W, and COAST-X Trials. Rheumatol Ther. 2026 Feb;13\(1\):279-291. doi: 10.1007/s40744-025-00810-5. Epub 2025 Dec 19. !\[\]\(bfa542c3db723395b50c17e412c2f440\_img.jpg\)](#)
- [Navarro-Compan V, Reveille JD, Rahman P, Maldonado-Cocco JA, Magrey M, Bolce R, Panni T, Kronbergs A, Rudwaleit M. Ixekizumab Improves Signs, Symptoms, and Quality of Life in Patients with Axial Spondyloarthritis Irrespective of Symptom Duration. Adv Ther. 2025 Sep;42\(9\):4706-4716. doi: 10.1007/s12325-025-03305-5. Epub 2025 Jul 22. !\[\]\(2a5474e70ac027d873e8a0f26c5b5459\_img.jpg\)](#)
- [Deodhar A, Poddubnyy D, Rahman P, Ermann J, Tomita T, Bolce R, Leage SL, Kronbergs A, Johnson C, Araujo J, Leung A, van der Heijde D. Long-Term Safety and Efficacy of Ixekizumab in Patients With Axial Spondyloarthritis: 3-year Data From the COAST Program. J Rheumatol. 2023 Aug;50\(8\):1020-1028. doi: 10.3899/jrheum.221022. Epub 2023 Feb 15. !\[\]\(4908edb166e79d0b50bc3204b03d60b5\_img.jpg\)](#)
- [Ortolan A, Ramiro S, Ramonda R, van der Heijde D. External validation of the alternative Ankylosing Spondylitis Disease Activity Score in three randomized clinical trials of ixekizumab. Rheumatology \(Oxford\). 2023 Jun 1;62\(6\):2257-2261. doi: 10.1093/rheumatology/keac618. !\[\]\(938ac72d35e769e9261f16c47d79809e\_img.jpg\)](#)
- [van der Horst-Bruinsma IE, de Vlam K, Walsh JA, Bolce R, Hunter T, Sandoval D, Zhu D, Geneus V, Soriano ER, Magrey M. Baseline Characteristics and Treatment Response to Ixekizumab Categorised by Sex in Radiographic and Non-radiographic Axial Spondylarthritis Through 52 Weeks: Data from Three Phase III Randomised Controlled Trials. Adv Ther. 2022 Jun;39\(6\):2806-2819. doi: 10.1007/s12325-022-02132-2. Epub 2022 Apr 16. !\[\]\(2d9b0a8721d13615195a490b3b29c19a\_img.jpg\)](#)
- [Maksymowych WP, Bolce R, Gallo G, Seem E, Geneus VJ, Sandoval DM, Ostergaard M, Tada K, Baraliakos X, Deodhar A, Gensler LS. Ixekizumab in radiographic axial spondyloarthritis with and without elevated C-reactive protein or positive magnetic resonance imaging. Rheumatology \(Oxford\). 2022 Nov 2;61\(11\):4324-4334. doi: 10.1093/rheumatology/keac104. !\[\]\(624a230017962d71b8a0cdb540ba9679\_img.jpg\)](#)
- [van der Heijde D, Ostergaard M, Reveille JD, Baraliakos X, Kronbergs A, Sandoval DM, Li X, Carlier H, Adams DH, Maksymowych WP. Spinal Radiographic Progression and Predictors of Progression in Patients With Radiographic Axial Spondyloarthritis Receiving Ixekizumab Over 2 Years. J Rheumatol. 2022 Mar;49\(3\):265-273. doi: 10.3899/jrheum.210471. Epub 2021 Dec 1. !\[\]\(c22f0da217890808fbd4818a43f6d62c\_img.jpg\)](#)
- [Deodhar AA, Mease PJ, Rahman P, Navarro-Compan V, Strand V, Hunter T, Bolce R, Leon L, Lauzon S, Marzo-Ortega H. Ixekizumab improves spinal pain, function, fatigue, stiffness, and sleep in radiographic axial Spondyloarthritis: COAST-V/W 52-week results. BMC Rheumatol. 2021 Sep 20;5\(1\):35. doi: 10.1186/s41927-021-00205-3. !\[\]\(cdebf62333066f71af5a8745d271bc91\_img.jpg\)](#)
- [Dougados M, Wei JC, Landewe R, Sieper J, Baraliakos X, Van den Bosch F, Maksymowych WP, Ermann J, Walsh JA, Tomita T, Deodhar A, van der Heijde D, Li X, Zhao F, Bertram CC, Gallo G, Carlier H, Gensler LS; COAST-V and COAST-W Study Groups. Efficacy and safety of ixekizumab through 52 weeks in two phase 3. randomised. controlled clinical trials in patients with active radiographic](#)

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- [Deodhar AA, Mease PJ, Rahman P, Navarro-Compan V, Strand V, Hunter T, Bolce R, Leon L, Lauzon S, Marzo-Ortega H. Ixekizumab improves spinal pain, function, fatigue, stiffness, and sleep in radiographic axial Spondyloarthritis: COAST-V/W 52-week results. BMC Rheumatol. 2021 Sep 20;5\(1\):35. doi: 10.1186/s41927-021-00205-3.](#)
- [Dougados M, Wei JC, Landewe R, Sieper J, Baraliakos X, Van den Bosch F, Maksymowych WP, Ermann J, Walsh JA, Tomita T, Deodhar A, van der Heijde D, Li X, Zhao F, Bertram CC, Gallo G, Carlier H, Gensler LS: COAST-V and COAST-W Study Groups. Efficacy and safety of ixekizumab through 52 weeks in two phase 3, randomised, controlled clinical trials in patients with active radiographic axial spondyloarthritis \(COAST-V and COAST-W\). Ann Rheum Dis. 2020 Feb;79\(2\):176-185. doi: 10.1136/annrheumdis-2019-216118. Epub 2019 Nov 4.](#)
- [Mease P, Walsh JA, Baraliakos X, Inman R, de Vlam K, Wei JC, Hunter T, Gallo G, Sandoval D, Zhao F, Dong Y, Bolce R, Marzo-Ortega H. Translating Improvements with Ixekizumab in Clinical Trial Outcomes into Clinical Practice: ASAS40, Pain, Fatigue, and Sleep in Ankylosing Spondylitis. Rheumatol Ther. 2019 Sep;6\(3\):435-450. doi: 10.1007/s40744-019-0165-3. Epub 2019 Jun 28.](#)
- [Deodhar A, Poddubnyy D, Pacheco-Tena C, Salvarani C, Lespessailles F, Rahman P, Jarvinen P, Sanchez-Burson J, Gaffney K, Lee EB, Krishnan E, Santisteban S, Li X, Zhao F, Carlier H, Reveille JD: COAST-W Study Group. Efficacy and Safety of Ixekizumab in the Treatment of Radiographic Axial Spondyloarthritis: Sixteen-Week Results From a Phase III Randomized, Double-Blind, Placebo-Controlled Trial in Patients With Prior Inadequate Response to or Intolerance of Tumor Necrosis Factor Inhibitors. Arthritis Rheumatol. 2019 Apr;71\(4\):599-611. doi: 10.1002/art.40753. Epub 2019 Mar 8.](#)

## Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

### Study Registration Dates

First Submitted

2016-02-26

First Submitted that Met QC Criteria

2016-02-26

First Posted (Estimated)

2016-03-02

### Results Reporting Dates

Results First Submitted

2019-09-24

Results First Submitted that Met QC Criteria

2019-10-25

Results First Posted

2019-10-30

### Certification/Extension Dates

Certification/Extension First Submitted

2018-06-05

Certification/Extension First Submitted that Met QC Criteria

2018-06-05

Certification/Extension First Posted

2018-06-08

### Study Record Updates

Last Update Submitted that Met QC Criteria

2020-06-10

Last Update Posted

2020-06-17

Last Verified

2020-06

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### Terms related to this study

Keywords Provided by Eli Lilly and Company

Ankylosing Spondylitis

Additional Relevant MeSH Terms

Spondylitis

Spinal Diseases

Bone Diseases

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Spondylitis  
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Musculoskeletal Diseases  
Arthritis  
Joint Diseases  
Axial Spondyloarthritis  
Spondylarthropathies  
Ankylosis  
Spondylarthritis  
Spondylitis, Ankylosing  
ixekizumab

## Plan for Individual Participant Data (IPD)

### Plan to Share Individual Participant Data (IPD)?

Yes

#### IPD Plan Description

Anonymized individual patient level data will be provided in a secure access environment upon approval of a research proposal and a signed data sharing agreement.

#### IPD Sharing Time Frame

Data are available 6 months after the primary publication and approval of the indication studied in the US and EU, whichever is later. Data will be indefinitely available for requesting.

#### IPD Sharing Url

<https://vivli.org/>

#### IPD Sharing Access Criteria

A research proposal must be approved by an independent review panel and researchers must sign a data sharing agreement.

#### IPD Sharing Supporting Information Type

Study Protocol  
Statistical Analysis Plan (SAP)  
Clinical Study Report (CSR)

## Drug and device information, study documents, and helpful links

### Study Documents Provided by Eli Lilly and Company

- [Study Protocol](#) [PDF, 1.32MB, 2017-06-02]
- [Statistical Analysis Plan](#) [PDF, 2.71MB, 2019-02-28]

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Arthritis

Joint Diseases

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