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A Study of Ixekizumab (LY2439821) in bDMARD-Naive Participants With Radiographic Axial Spondyloarthritis (COAST-V)

Completed ⓘ

No longer looking for participants

ClinicalTrials.gov ID ⓘ NCT02696785

Sponsor ⓘ Eli Lilly and Company

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

Last Update Posted ⓘ 2019-11-19

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Study Overview

Brief Summary

The main purpose of this study is to evaluate the safety and efficacy of the study drug known as ixekizumab in biological disease-modifying anti-rheumatic drugs (bDMARDs)-naive participants with radiographic axial spondyloarthritis (rad-axSpA).

Official Title

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

Conditions ⓘ

Spondyloarthritis

Intervention/Treatment ⓘ

- Drug: Ixekizumab
- Drug: Placebo
- Drug: Adalimumab

Other Study ID Numbers ⓘ

- 16178
- 11F-MC-RHBV (Other Identifier) (OTHER: Eli Lilly and Company)
- 2015-003932-11 (EudraCT Number)

Study Start (Actual) ⓘ

2016-05-02

Primary Completion (Actual) ⓘ

2017-12-08

Study Completion (Actual) ⓘ

2018-10-17

Enrollment (Actual) ⓘ

341

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine



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- 16178
- I1F-MC-RHBV (Other Identifier) (OTHER: Eli Lilly and Company)
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[Drug Information](#) available for: [Ixekizumab](#) [Adalimumab](#)

[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 28 locations

United States

Arizona Locations

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

California Locations

- 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

- Trumbull, Connecticut, United States, 06611
New England Research Associates

Florida Locations

- Sarasota, Florida, United States, 34239
Sarasota Arthritis Center

Georgia Locations

- Marietta, Georgia, United States, 30060
Marietta Rheumatology

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
Klein and Associates MD, PA

Missouri Locations

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

Montana Locations

- Kalispell, Montana, United States, 59901
Clarke View Research Institute





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Missouri Locations

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

Montana Locations

- Kalispell, Montana, United States, 59901**
Glacier View Research Institute

Nebraska Locations

- Lincoln, Nebraska, United States, 68516**
Physician Research Collaboration, LLC

North Carolina Locations

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

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

Washington Locations

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

Czechia

- Brno, Czechia, 611 41**
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, 12203**
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, 366 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

Netherlands

- Warszawa, Netherlands, 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.

South Korea

- Gwangjin-gu, South Korea, 05080**
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.
- Seoul, South Korea, 04763**
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.

Taiwan

- Taichung, Taiwan, 40201**
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.
- Taichung, Taiwan, 40447**
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.
- Taipei, Taiwan, 10048**
For additional information regarding investigative sites for this trial, contact 1-877-



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This study has 28 locations

**Taichung, Taiwan, 40447**

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.

**Taipei, Taiwan, 10048**

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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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.
- 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 ≥ 3 months with age at onset < 45 years.
- In the past had an inadequate response to at least 2 non-steroidal anti-inflammatory drugs (for duration 4 weeks) or cannot tolerate NSAIDs.
- If taking NSAIDs be on a stable dose for at least 2 weeks prior to randomization.
- 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 received any prior, or are currently receiving, treatment with biologics, tumor necrosis factor inhibitors or other immunomodulatory agents.
- 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 study.
- Are pregnant or breastfeeding.

Ages Eligible for Study ¹

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study ¹

All

Accepts Healthy Volunteers ¹

No

Study Plan

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

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How is the study designed?

Design Details

Primary Purpose ¹ : Treatment

Allocation ¹ : Randomized

Interventional Model ¹ : Parallel Assignment

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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 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. Extended Treatment Period: 80 mg ixekizumab given SC Q2W from week 16 to week 52.	Drug: Ixekizumab - Administered SC - Other Names: - LY2439821
Experimental: Q4W Ixekizumab 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. Extended Treatment Period: 80 mg ixekizumab given SC Q4W from week 16 to week 52.	Drug: Ixekizumab - Administered SC - Other Names: - LY2439821
Placebo Comparator: Placebo Double Blind Period: Placebo given SC Q2W to week 14. Extended Treatment Period: 80 mg ixekizumab given SC Q2W or Q4W from week 16 to week 52.	Drug: Ixekizumab - Administered SC - Other Names: - LY2439821 Drug: Placebo - Administered SC
Active Comparator: Adalimumab Double Blind Period: 40 mg Adalimumab given SC Q2W to week 14. Extended Treatment Period: 80 mg ixekizumab given SC Q2W or Q4W from week 20 to week 52.	Drug: Ixekizumab - Administered SC - Other Names: - LY2439821 Drug: Adalimumab - Administered SC

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
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What is the study measuring?

Primary Outcome Measures ¹

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) Response	ASAS40 is defined as improvement from baseline of greater than or equal to ($\geq$) 40% and absolute improvement from baseline of at least 2 units in at least 3 of the following 4 domains without any worsening in the remaining domains. 1. Patient Global: How active was your spondylitis on average during the last week? score range 0 (not active) to 10 (very active). 2. Spinal Pain: How much Pain of your spine due to Ankylosing spondylitis? score ranges 0 (no pain) to 10 (severe pain). 3. Bath Ankylosing Spondylitis Functional Index: Participant is asked to rate the difficulty associated with 10 individual basic functional activities. Participants response is captured using numeric rating scale (NRS) scale (range 0 to 10) with a higher score indicating worse function. 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).	Week 16

Secondary Outcome Measures ¹

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving an ASAS20 Response	ASAS20 response is defined as a $\geq$20% improvement and an absolute improvement from baseline of $\geq$1 units in $\geq$3 of 4 following domains and no worsening of $\geq$20% and $\geq$1 unit (range 0 to 10) in the remaining domain. 1. Patient Global: How active was your spondylitis on average during the last week? score range 0 (not active) to 10 (very active). 2. Spinal Pain: How much Pain of your spine due to Ankylosing spondylitis? score ranges 0 (no pain) to 10 (severe pain). 3. Bath Ankylosing Spondylitis Functional Index: Participant is asked to rate the difficulty associated with 10 individual basic functional activities. Participants response is captured using NRS scale (range 0 to 10) with a higher score indicating worse function. 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).	Week 16
Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)	ASDAS is a composite index to assess disease activity in AS. The parameters used for the ASDAS (with CRP as acute phase reactant) are the following: 1. Total back pain 2. Patient global 3. Peripheral pain/swelling 4. Duration of morning stiffness 5. CRP in mg/L The ASDAScrp is calculated with the following equation: $0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \text{Ln}(\text{CRP}+1)$ CRP is in mg/liter, the range of other variables is from 0 to 10. Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher scores indicated higher disease	Baseline, Week 16

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	4. Duration of morning stiffness 5. CRP in mg/L The ASDASCrp is calculated with the following equation: $0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \ln(\text{CRP}+1)$. CRP is in mg/liter, the range of other variables is from 0 to 10. Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher scores indicated higher disease activity. Ln represents the natural logarithm. Least Square (LS) Mean was calculated using mixed model repeated measures (MMRM) model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	
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 measuring discomfort, pain, and fatigue. 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). BASDAI50 represents an improvement of $\geq 50\%$ of the BASDAI score from baseline.	Week 16
Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI)	The BASFI is a participant-reported assessment that establishes a participants functional baseline and subsequent response to treatment. To complete the BASFI, a participant is asked to rate the difficulty associated with 10 individual basic functional activities. Participants respond to each question using an NRS scale (range 0 to 10) with a higher score indicating worse function. The participants final BASFI score is the mean of the 10 item scores has a possible minimum value of 0 and a possible maximum value of 10, with a higher score indicating worse function. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
Percentage of Participants Achieving ASDAS Inactive Disease	ASDAS is a composite index to assess disease activity in AS. The parameters used for the ASDAS (with CRP as acute phase reactant) are the following: 1. Total back pain 2. Patient global 3. Peripheral pain/swelling 4. Duration of morning stiffness 5. CRP in mg/L The ASDASCrp is calculated with the following equation: $0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \ln(\text{CRP}+1)$. CRP is in mg/liter, the range of other variables is from 0 to 10. Data from five variables combined to yield a score (0.6361 to no defined upper limit), where higher scores indicated higher disease activity. Ln represents the natural logarithm. ASDAS Inactive Disease is defined as a score of < 1.3.	Week 16
Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Ankylosing Spondylitis Spinal Magnetic	The Berlin modification of Ankylosing Spondylitis spine MRI score for activity (ASspiMRI) scoring technique assesses inflammation in each of 23 disco-vertebral units (DVU). All 23 disco-vertebral units (DVU) of the spine (from C2 to S1) are scored for bone marrow edema. Scores for each DVU range from 0-2 (0=normal; 1=mild bone marrow edema; 2=severe bone marrow edema).	Baseline, Week 16

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Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Ankylosing Spondylitis Spinal Magnetic Resonance Imaging [ASSpiMRI] - Berlin Score)	The Berlin modification of Ankylosing Spondylitis spine MRI score for activity (ASSpiMRI) scoring technique assesses inflammation in each of 23 disco-vertebral units (DVU). All 23 disco-vertebral units (DVU) of the spine (from C2 to S1) are scored for 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. Least Squares (LS) Mean was calculated using ANCOVA model with treatment, geographic region, baseline CRP status and baseline value as fixed factors.	Baseline, 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 calculated using MMRM model with treatment, geographic region, baseline CRP status, 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)	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 one question that the participant needs to respond to with either "I agree" (score of 1) or "I do not agree" (score of 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. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors	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 will be measured with a high sensitivity assay at the central laboratory to help assess the effect of Ixekizumab on disease activity. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, visit and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
Change From Baseline in Mobility on the Bath Ankylosing Spondylitis Metrology Index (BASMI)	The BASMI is a combined index comprising the following 5 clinical measurements of spinal mobility in participants with rad-axSpA. 1. Lateral spinal flexion 2. Tragus-to-wall distance 3. Lumbar flexion (modified Schrober) 4. Maximal intermalleolar distance 5. Cervical rotation. The BASMI includes these 5 measurements that are each scaled to a score of 0 to 10 depending on the result of the assessment (BASMI linear function). The average score of the 5 assessments gives the BASMI linear result. The higher the BASMI	Baseline, Week 16

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	2. Tragus-to-wall distance 3. Lumbar flexion (modified Schrober) 4. Maximal intermalleolar distance 5. Cervical rotation. The BASMI includes these 5 measurements that are each scaled to a score of 0 to 10 depending on the result of the assessment (BASMI linear function). The average score of the 5 assessments gives the BASMI linear result. The higher the BASMI score the more severe the participants limitation of movement due to their AS. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	
Change From Baseline in Chest Expansion	While participants have their hands resting on or behind the head, the assessor has measured the chest's encircled length by centimeter at the fourth intercostal level anteriorly. The difference between maximal inspiration and expiration in centimeters was recorded. Two tries were recorded. The better measurement (larger difference) of 2 tries (in centimeters) was used for analyses. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
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. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
Change From Baseline in MRI Sacroiliac Joint(s) (SIJ) Spondyloarthritis Research Consortium of Canada (SPARCC) Score	Both left and right SIJ are scored for bone marrow edema. Each side has 6 slices and each slice has 6 scoring units, and each scoring unit has a score of 0 or 1. Total SIJ SPARCC scores can range from 0 to 72 with higher scores reflecting worse disease. LSMean was calculated using ANCOVA model with treatment, geographic region, baseline CRP status and baseline value 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. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
Change From Baseline in 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 I / D), Lateral epicondyle (I / D), Suprapatellar insertion into	Baseline, Week 16

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	treatment-by-visit interaction as fixed factors.	
Change From Baseline in 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. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, 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 (TJC)	The number of tender and painful joints was determined by examination of 46 joints (23 joints on each side of the participants body. The 46 joints are assessed and classified as tender or not tender. sum of all joints checked to be tender/painful divided by number of evaluable joints which is multiplied by 46 to obtain TJC score. The scores ranges from 0 (no tender/painful joints) to 46 (all joints tender/painful). LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	Baseline, Week 16
Number of Participants With Anterior Uveitis or Uveitis Flares	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.	Baseline through 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 one number that describes their worst level of fatigue during the previous 24 hours. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, 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 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. Participants report the number 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. LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, 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	The WPAI-SpA consists of 6 questions to determine employment status, hours missed from work because of SpA, hours missed from work for other	Baseline, Week 16

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	LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction as fixed factors.	
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. Greater scores indicate greater impairment and less productivity. LSMean was calculated using ANCOVA model with treatment, geographic region, baseline CRP status 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).. ASAS-NSAID score=(equivalent NSAID score)x(days of intake during PI)x(days per week)/(PI in days). Higher scores indicate greater NSAIDs intake. 0= no intake, 100 = equivalent NSAID intake.	Baseline, Week 52
Number of Participants With Anti Ixekizumab Antibodies	A treatment emergent - antidrug antibody (TE-ADA) positive patient is defined as: a) a patient with a ≥ 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 $\geq 1:10$.	Week 16
Pharmacokinetics: Trough Ixekizumab Concentration at Steady State (C _{trough} ss)		Week 16
Change From Baseline in Severity of Peripheral Arthritis by Swollen Joint Count (SJC)	The number of swollen joints was determined by examination of 44 joints (22 joints on each side of the participants body. The 44 joints are assessed and classified as swollen or not swollen. "sum of all joints checked to be swollen" divided by "number of evaluable joints" and then multiplied by 44 to obtain SJC score. The SJC score ranges from 0 (no swollen joints) to 44 (all joints swollen). LSMean was calculated using MMRM model with treatment, geographic region, baseline CRP status, baseline value, visit, baseline value-by-visit, and treatment-by-visit interaction 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 (DVUs) of the spine (from C2 to S1) are scored for bone marrow edema. A single DVU has a scoring range of 0 to 18, bringing the maximum total score to 414, with higher scores reflecting worse disease. Scoring was performed by central readers. LSMean was calculated using ANCOVA model with treatment, geographic region, baseline CRP status and baseline value as fixed factors	Baseline, Week 16

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Collaborators and Investigators

Document title: Study Details | NCT02696785 | A Study of Ixekizumab (LY2439821) in bDMARD-Naive Participants With Radiographic Axial Spondyloarthritis |...

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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.

- [Sengupta R, Machado PM, Goupille P, Rudwaleit M, Sheesh M, Ng KJ, Ngantcha M, Yan Y, Russ H, Doridot G, Xue Y, Poddubnyy D, Baraliakos X, Navarro-Compan V. Efficacy of Ixekizumab in Radiographic Axial Spondyloarthritis by Baseline C-Reactive Protein Level: A Pooled Analysis of Phase III Trials. Rheumatol Ther. 2026 Jun 2. doi: 10.1007/s40744-026-00862-1. Online ahead of print.](#)
- [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.](#)
- [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.](#)
- [Maksymowych WP, Lambert RGW, Bolce RJ, Bello N, Zhu B, Lisse JR, Ostergaard M. The effect of ixekizumab treatment on MRI sacroiliac joint structural lesions in patients with radiographic axial spondyloarthritis: post-hoc analysis of a 52-week, randomised, placebo-controlled trial with an active reference arm. Lancet Rheumatol. 2025 May;7\(5\):e314-e322. doi: 10.1016/S2665-9913\(24\)00312-6. Epub 2025 Feb 18.](#)
- [Ramiro S, Lukas C, Nissen MJ, Zhu B, Ng KJ, Sheesh M, Doridot G, Liu-Leage S, Chan A, Fang Y, Wei JC. Improvement in spinal pain at night and its impact on long-term outcomes in radiographic axial spondyloarthritis: Results from Ixekizumab COAST-V randomised trial. Semin Arthritis Rheum. 2024 Dec;69:152571. doi: 10.1016/j.semarthrit.2024.152571. Epub 2024 Oct 23.](#)
- [Ramiro S, Lukas C, Bessette L, Wickersham P, Panni T, Bolce R, Liu-Leage S, Janos B, Nissen MJ, Wei JC. Early clinical response associates with long-term outcomes with ixekizumab in radiographic axial spondyloarthritis. RMD Open. 2024 Jul 14;10\(3\):e004429. doi: 10.1136/rmdopen-2024-004429.](#)
- [de Vlam K, Maksymowych WP, Gallo G, Rahman P, Mease P, Krishnan V, McVeigh CJ, Lisse J, Zhu D, Bolce RJ, Conaghan PG. Exploring the Effects of Ixekizumab on Pain in Patients with Ankylosing Spondylitis Based on Objective Measures of Inflammation: Post Hoc Analysis from a Large Randomized Clinical Trial. Rheumatol Ther. 2024 Jun;11\(3\):691-707. doi: 10.1007/s40744-024-00660-7. Epub 2024 Apr 18.](#)
- [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.](#)
- [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.](#)
- [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.](#)

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- [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.](#)
- [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.](#)
- [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 spondylarthritis 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.](#)
- [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 Spondylarthritis Receiving Ixekizumab Over 2 Years. J Rheumatol. 2022 Mar;49\(3\):265-273. doi: 10.3899/jrheum.210471. Epub 2021 Dec 1.](#)
- [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 Spondylarthritis: 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 spondylarthritis \(COAST-V and COAST-W\). 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.](#)

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

Certification/Extension Dates

Certification/Extension First Submitted

2018-06-04

Certification/Extension First Submitted that Met QC Criteria

2018-06-04

Certification/Extension First Posted

2018-06-08

Results Reporting Dates

Results First Submitted

2019-09-24

Results First Submitted that Met QC Criteria

2019-10-31

Results First Posted

2019-11-19

Study Record Updates

Last Update Submitted that Met QC Criteria

2019-10-31

Last Update Posted

2019-11-19

Last Verified

2018-11

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Terms related to this study

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Ankylosing Spondylitis

Additional Relevant MeSH Terms

Spondylitis
Spinal Diseases
Bone Diseases
Musculoskeletal Diseases
Arthritis
Joint Diseases
Axial Spondyloarthritis
Spondylarthropathies
Ankylosis
Spondylarthritis
Spondylitis, Ankylosing
Antibodies, Monoclonal, Humanized
Antibodies, Monoclonal
Antibodies
Immunoglobulins
Immunoproteins
Blood Proteins
Proteins
Amino Acids, Peptides, and Proteins
Serum Globulins
Globulins
ixekizumab
Adalimumab

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

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Serum Globulins
Globulins
ixekizumab
Adalimumab

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- [Study Protocol](#) [PDF, 2.13MB, 2016-12-23]
- [Statistical Analysis Plan](#) [PDF, 2.21MB, 2018-10-16]

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