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Completed

Study of Adalimumab in Patients With Axial Spondyloarthritis

ClinicalTrials.gov ID NCT00939003

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2014-09-09

Study Overview

Brief Summary

This study will evaluate how well adalimumab works in the short and long term in patients with axial spondyloarthritis who are not diagnosed as having either ankylosing spondylitis or psoriatic arthritis.

Detailed Description

This is a Phase 3, placebo-controlled, double-blind randomized study with an open-label phase designed to evaluate the efficacy and safety of adalimumab 40 mg administered every other week in adult patients with active axial spondyloarthritis (SpA) who are not diagnosed with ankylosing spondylitis, psoriasis, or psoriatic arthritis and who have had an inadequate response or intolerance to one or more nonsteroidal anti-inflammatory drugs (NSAIDs) or had a contraindication to NSAIDs. Participants receive adalimumab or placebo for 12 weeks during the double-blind phase of the study. Following the double-blind phase, all remaining participants enter the open-label phase of the study in which they receive open-label adalimumab for up to 144 weeks. Efficacy endpoints include the Assessment of Spondyloarthritis International Society (ASAS) response criteria for patients with SpA. These response criteria were used to determine participants who were responders. ASAS response involves evaluations in the following 4 domains: participant's global assessment of disease activity, pain, function, and inflammation. The patient's global assessment of disease activity score is assessed using a 100 millimeter (mm) visual analog scale (VAS; 0 for no disease activity to 100 for severe disease activity). Pain is represented as a total back pain score and is

Study Start
2009-07

Primary Completion (Actual)
2011-02

Study Completion (Actual)
2013-08

Enrollment (Actual)
192

Study Type
Interventional

Phase
Phase 3

Janssen Biotech, Inc.
Exhibit 2059
Accord v. Janssen
IPR2026-00259
Ex. 2059-001

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criteria for patients with SpA. These response criteria were used to determine participants who were responders. ASAS response involves evaluations in the following 4 domains: participant's global assessment of disease activity, pain, function, and inflammation. The patient's global assessment of disease activity score is assessed using a 100 millimeter (mm) visual analog scale (VAS; 0 for no disease activity to 100 for severe disease activity). Pain is represented as a total back pain score and is assessed using a 100 mm VAS (0 for no pain to 100 for most severe pain). Function score is represented as the Bath Ankylosing Spondylitis (AS) Functional Index (BASFI) 100 mm VAS score (average of the ability to perform 10 activities, each scored as 0 for easy to 100 for impossible). Inflammation is determined using the morning stiffness overall level score (0 for none to 10 for very severe) and duration score (0 for 0 hours to 10 for ≥ 2 hours) of the Bath AS Disease Activity Index (BASDAI) (mean of these items #5 and #6 scores). In addition, the BASDAI is used as an efficacy endpoint. The BASDAI is used by the participant to assess his/her disease activity. Using VAS scales, the participant answers 6 questions pertaining to symptoms experienced over the past week. For 5 questions (levels of: fatigue/tiredness; AS neck, back, or hip pain; pain/swelling; discomfort at areas tender to touch or pressure; and morning stiffness), the response scale is 0 (none) to 10 (very severe). For 1 question (duration of morning stiffness), the response scale is 0 (0 hours) to 10 (≥ 2 or more hours).

Phase 3

Official Title

A Multicenter Study of the Efficacy and Safety of the Human Anti-TNF Monoclonal Antibody Adalimumab in Subjects With Axial Spondyloarthritis

Conditions

Axial Spondyloarthritis

Intervention / Treatment

- Biological: Adalimumab
- Biological: Placebo
- Biological: Open-label Adalimumab

Other Study ID Numbers

- M10-791
- 2009-010643-14 (EudraCT Number)

Resource links provided by the National Library of Medicine NIH NLM

Drug Information available for: 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 38 locations

United States

Alabama Locations



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This study has 38 locations



United States

Alabama Locations

Birmingham, Alabama, United States, 35205
Site Reference ID/Investigator# 21250

Colorado Locations

Colorado Springs, Colorado, United States, 80910
Site Reference ID/Investigator# 21249

Denver, Colorado, United States, 80230
Site Reference ID/Investigator# 21245

Maryland Locations

Wheaton, Maryland, United States, 20902
Site Reference ID/Investigator# 21246

Pennsylvania Locations

Duncansville, Pennsylvania, United States, 16635
Site Reference ID/Investigator# 26582

Wyomissing, Pennsylvania, United States, 19610
Site Reference ID/Investigator# 21241

Texas Locations

Dallas, Texas, United States, 75231
Site Reference ID/Investigator# 21243

Houston, Texas, United States, 77030
Site Reference ID/Investigator# 21248

Washington Locations

Seattle, Washington, United States, 98122
Site Reference ID/Investigator# 21247

Australia

Brisbane, Australia, 4102
Site Reference ID/Investigator# 22342

Kogarah, Australia, 2217
Site Reference ID/Investigator# 21223

Maroochydore, Australia, 4558
Site Reference ID/Investigator# 21222

Belgium

Genk, Belgium, 3600
Site Reference ID/Investigator# 21225

Ghent, Belgium, 9000
Site Reference ID/Investigator# 21224

Gilly, Belgium, 6060
Site Reference ID/Investigator# 26544

Merksem, Belgium, 2170
Site Reference ID/Investigator# 27382

Canada

Edmonton, Canada, T6G 2S2
Site Reference ID/Investigator# 21229

Sainte-Foy, Quebec, Canada, G1W 4R4
Site Reference ID/Investigator# 21226

St. John's, Canada, A1C 5B8
Site Reference ID/Investigator# 21227

Toronto, Canada, M5T 2S8
Site Reference ID/Investigator# 21228

Czechia

Brno, Czechia, 65691
Site Reference ID/Investigator# 21231

Pardubice, Czechia, 530 02
Site Reference ID/Investigator# 26882

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Czechia

- **Brno, Czechia, 65691**
  Site Reference ID/Investigator# 21231
- **Pardubice, Czechia, 530 02**
  Site Reference ID/Investigator# 26882
- **Prague, Czechia, 128 50**
  Site Reference ID/Investigator# 21230
- **Uherské Hradiště, Czechia, 686 01**
  Site Reference ID/Investigator# 26883

France

- **Boulogne-Billancourt, France, 92100**
  Site Reference ID/Investigator# 21263
- **Chambray-les-Tour, France, 37170**
  Site Reference ID/Investigator# 21262
- **Orléans, France, 45067**
  Site Reference ID/Investigator# 21261
- **Paris, France, 75679**
  Site Reference ID/Investigator# 22343

Germany

- **Berlin, Germany, 12200**
  Site Reference ID/Investigator# 21266
- **Erlangen, Germany, 91054**
  Site Reference ID/Investigator# 21267
- **Herne, Germany, 44652**
  Site Reference ID/Investigator# 21264
- **Munich, Germany, 80336**
  Site Reference ID/Investigator# 21265

Netherlands

- **Amsterdam, Netherlands, 1105 AZ**
  Site Reference ID/Investigator# 21285
- **Leiden, Netherlands, 2333 ZA**
  Site Reference ID/Investigator# 21284

Spain

- **A Coruña, Spain, 15006**
  Site Reference ID/Investigator# 21282
- **Barcelona, Spain, 08907**
  Site Reference ID/Investigator# 21283
- **Córdoba, Spain, 14004**
  Site Reference ID/Investigator# 21281

United Kingdom

- **Newcastle upon Tyne, United Kingdom, NE7 7DN**
  Site Reference ID/Investigator# 21289

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	Ages Eligible for Study
	18 Years and older (Adult, Older

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For general information about clinical research, read Learn About Studies.

Eligibility Criteria

Description

Inclusion Criteria:

- Adult patients with inadequate response to >/= 1 non-steroidal anti-inflammatory drugs (NSAIDs)
- Chronic back pain with onset < 45 years of age
- Magnetic resonance imaging (MRI) indicating active sacroiliitis or positive human leukocyte antigen-B27 (HLA-B27) blood test in addition to meeting spondyloarthritis clinical criteria
- Negative purified protein derivative (PPD) test and chest x-ray performed at Baseline visit must be negative
- Ability to administer subcutaneous injections
- General good health otherwise

Exclusion Criteria:

- Prior anti-tumor necrosis factor (TNF) therapy
- Psoriasis or psoriatic arthritis
- Fulfillment of modified New York criteria for ankylosing spondylitis
- Recent infection requiring treatment
- Significant medical events or conditions that may put patients at risk for participation
- Females who are pregnant or breast-feeding or considering becoming pregnant during the study
- History of cancer, except successfully treated skin cancer
- Recent history of drug or alcohol abuse

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

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 : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Adalimumab	Biological: Adalimumab • 40 mg every other week up to Week 12 • Other Names: ◦ ABT-D2E7

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Experimental: Adalimumab	Biological: Adalimumab • 40 mg every other week up to Week 12 • Other Names: ◦ ABT-D2E7 ◦ Humira
Placebo Comparator: Placebo	Biological: Placebo • Placebo every other week up to Week 12
Experimental: Open-label Adalimumab	Biological: Open-label Adalimumab • 40 mg every other week, Week 12 through Week 156 • Other Names: ◦ ABT-D2E7 ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Achieving an Assessment of Spondyloarthritis International Society (ASAS) 40 Response	ASAS40 response was defined as improvement of ≥ 40% relative to Baseline and absolute improvement of ≥ 20 units (on a scale from 0 to 100) in ≥ 3 of the following 4 domains with no deterioration (defined as a net worsening of > 0 units on a scale from 0 to 100) in the potential remaining domain: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none/0 hours) to 10 (very severe/2 hours or more duration).	Baseline and Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Achieving an Assessment of Spondyloarthritis	ASAS20 response was defined as improvement of ≥ 20% relative to Baseline and absolute improvement of ≥ 10 units (on a scale from 0 to 100) in ≥ 3 of the following 4 domains with no deterioration (defined as a change for the worse of ≥ 20% and net worsening of ≥	Baseline and Week 12

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Outcome Measure	Measure Description	Time Frame
Number of Participants Achieving an Assessment of Spondyloarthritis International Society (ASAS) 20 Response	ASAS20 response was defined as improvement of ≥ 20% relative to Baseline and absolute improvement of ≥ 10 units (on a scale from 0 to 100) in ≥ 3 of the following 4 domains with no deterioration (defined as a change for the worse of ≥ 20% and net worsening of ≥ 10 units) in the potential remaining domain: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none/0 hours) to 10 (very severe/2 hours or more duration).	Baseline and Week 12
Number of Participants Achieving a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) 50 Response	The Bath Ankylosing Spondylitis (AS) Disease Activity Index assesses disease activity by asking the participant to answer 6 questions (each on a 10 cm VAS) pertaining to symptoms experienced for the past week. For 5 questions (level of fatigue/tiredness, level of AS neck, back or hip pain, level of pain/swelling in joints, other than neck, back or hips, level of discomfort from any areas tender to touch or pressure, and level of morning stiffness), the response is from 0 (none) to 10 (very severe); for Question 6 (duration of morning stiffness), the response is from 0 (0 hours) to 10 (≥ 2 hours). The overall BASDAI score ranges from 0 to 10 cm. Lower scores indicate less disease activity. BASDAI50 is a 50% improvement from Baseline in BASDAI score.	Baseline and Week 12
Change From Baseline in Short Form-36 (SF-36) Physical Component Summary Score	The Medical Outcome Study Short Form 36-Item Health Survey, Version 2 (SF-36) is a self-administered instrument that measures the impact of disease on overall quality of life. The SF-36 consists of 36 questions in 8 domains (limitations in physical functioning due to health problems; limitations in usual role because of physical health problems; bodily pain; general health perceptions; vitality; limitations in social functioning because of physical or emotional problems; limitations in usual role due to emotional problems; and general mental health). Two component scores can be summarized: physical and mental; domains 1-4 comprise the physical component summary of the SF-36. A transformed summary score is calculated ranging from 0 to 100 where higher scores indicate a higher level of functioning. A positive change from Baseline score indicates an improvement.	Baseline and Week 12
Number of Participants Achieving ASAS Partial Remission	ASAS partial remission is an absolute score of < 20 units on a 0 to 100 scale for each of the four following domains: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis	Week 12

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Achieving ASAS Partial Remission	100 scale for each of the four following domains: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none/0 hours) to 10 (very severe/2 hours or more duration).	
Number of Participants Achieving an ASAS5/6 Response	ASAS5/6 response is a 20% improvement in five out of the following six domains: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none) to 10 (very severe/2 hours or more duration). • Spinal mobility, measured from the lateral lumbar flexion score of the Bath AS Metrology Index (BASMI) on a scale from 0 (best mobility) to 10 (worst mobility); • C-reactive protein level (lower levels indicate less inflammation).	Baseline and Week 12
Change From Baseline in Disability Index of Health Assessment Questionnaire Modified for the Spondyloarthropathies (HAQ-S)	Health Assessment Questionnaire modified for spondyloarthropathies (HAQ-S) is a self-reported measure to assess the physical function and health-related quality of life. The Disability Index (DI) of HAQ-S is calculated as the mean of the following 8 category scores (range: 0 [without any difficulty] to 3 [unable to do]): Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. Five additional items in the functional status measure were included in the HAQ-S, including carrying heavy packages, sitting for long periods, able to work at a flat topped table, and (if the participant had a driver's license or a car) able to look in the rear view mirror and able to turn head to drive in reverse. The overall score ranges from 0 (no disability) to 3 (three very severe, high-dependency disability). Negative mean changes from Baseline in the overall score indicate improvement.	Baseline and Week 12
Change From Baseline in High-Sensitivity C-Reactive Protein (hsCRP)	C-reactive protein (CRP) is considered an efficacy variable for the axial spondyloarthritis indication. It is a general marker of inflammation that is sensitive to acute changes in inflammatory response. Higher levels indicate more inflammation.	Baseline and Week 12

	In the overall score indicate improvement.	
Change From Baseline in High-Sensitivity C-Reactive Protein (hsCRP)	C-reactive protein (CRP) is considered an efficacy variable for the axial spondyloarthritis indication. It is a general marker of inflammation that is sensitive to acute changes in inflammatory response. Higher levels indicate more inflammation.	Baseline and Week 12
Change From Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Magnetic Resonance Imaging (MRI) Score for Sacroiliac Joints	Six consecutive sacroiliac (SI) joint image coronal slices representing the largest proportion of the synovial compartment of the SI joints were assessed for edema, intensity and depth of edema using SPARCC scoring. Each SI joint (left and right) was divided into quadrants for a total of 8 SI scoring locations. Each quadrant was scored for the presence (1) or absence (0) of edema; the maximum score is 8 per slice and maximum score for 6 SI joint slices is 48. Intensity of edema: A score of 1 was assigned for each SI joint (left and right) if an intense signal was seen in any quadrant of that joint for each slice. The maximum score is 2 per slice and 12 for 6 slices. A lesion was graded as deep (score of 1) if there was homogeneous and unequivocal increase in signal extending over a depth of at least 1 cm from the articular surface of the SI joint in any quadrant. The maximum score per slice is 2 and for 6 slices 12. The total maximum score for all SI joints across 6 slices is 72.	Baseline and Week 12
Change From Baseline in SPARCC MRI Score for the Spine	Six discovertebral units (DVU) representing the 6 most abnormal DVUs, and 3 consecutive sagittal slices at each DVU representing the most abnormal slices for that DVU were selected for scoring. Each DVU was divided into 4 quadrants and scored for the presence (1) or absence (0) of edema. The maximum score is 12 per DVU. The maximum score is 72 for 6 DVUs. If edema was present in at least 1 quadrant of a DVU slice, it was scored for intensity and depth of the edema representing that slice: A score of 1 was assigned if an intense signal was seen in any quadrant on a DVU slice. The maximum score for intensity per slice is 1, per DVU is 3 and for 6 DVUs is 18. A lesion was graded as deep (score of 1) if there was homogeneous and unequivocal increase in signal extending over a depth of at least 1 cm from the surface of the endplate in any quadrant. The maximum score per slice is 1, for a DVU is 3 and for 6 DVUs is 18. The total maximum SPARCC score for all 6 DVUs is 108.	Baseline and Week 12

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Reporting Adverse Events	Adverse events were collected at designated study visits for all participants who received at least 1 dose of study drug. The number of participants experiencing any adverse event (serious and non-serious) is summarized.	Through Week 12

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Number of Participants Reporting Adverse Events	Adverse events were collected at designated study visits for all participants who received at least 1 dose of study drug. The number of participants experiencing any adverse event (serious and non-serious) is summarized.	Through Week 12
Number of Participants With Blood Hematology or Chemistry Values Common Toxicity Criteria Grade ≥ 3	Blood was collected for analysis at designated study visits; hematology and chemistry results were provided by a central laboratory. The number of participants with an abnormal laboratory result (higher then upper normal limit or lower than lower normal limit) meeting Common Toxicity Criteria (CTC) of Grade 3 or higher is summarized.	Through Week 12
Number of Participants Achieving an ASAS20 Response During the Open-label Period	ASAS20 response was defined as improvement of ≥ 20% relative to Baseline and absolute improvement of ≥ 10 units (on a scale from 0 to 100) in ≥ 3 of the following 4 domains with no deterioration (defined as a change for the worse of ≥ 20% and net worsening of ≥ 10 units) in the potential remaining domain: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none/0 hours) to 10 (very severe/2 hours or more duration).	Baseline and Weeks 52, 104, and 156
Number of Participants Achieving an ASAS40 Response During the Open-label Period	ASAS40 response was defined as improvement of ≥ 40% relative to Baseline and absolute improvement of ≥ 20 units (on a scale from 0 to 100) in ≥ 3 of the following 4 domains with no deterioration (defined as a net worsening of > 0 units on a scale of 0 to 100) in the potential remaining domain: • Patient's Global Assessment of disease activity, measured on a visual analog scale (VAS) from 0 (none) to 100 (severe); • Pain, measured by the total back pain VAS from 0 (no pain) to 100 (most severe); • Function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) which consists of 10 items assessing participants' ability to perform activities on a VAS ranging from 0 (easy) to 100 (impossible); • Inflammation, measured by the mean of the 2 morning stiffness-related Bath AS Disease Activity Index (BASDAI) VAS scores (items 5 [level of stiffness] and 6 [duration of stiffness]) each on a scale from 0 (none/0 hours) to 10 (very severe/2 hours or more duration).	Baseline and Weeks 52, 104, and 156
Number of Participants Achieving a BASDAI50 Response During the Open-label Period	The Bath Ankylosing Spondylitis (AS) Disease Activity Index assesses disease activity by asking the participant to answer 6 questions (each on a 10 cm VAS) pertaining to symptoms experienced for the past week. For 5 questions (level of	Baseline and Weeks 52, 104, and 156

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	hours or more duration).	
Number of Participants Achieving a BASDAI50 Response During the Open-label Period	The Bath Ankylosing Spondylitis (AS) Disease Activity Index assesses disease activity by asking the participant to answer 6 questions (each on a 10 cm VAS) pertaining to symptoms experienced for the past week. For 5 questions (level of fatigue/tiredness, level of AS neck, back or hip pain, level of pain/swelling in joints, other than neck, back or hips, level of discomfort from any areas tender to touch or pressure, and level of morning stiffness), the response is from 0 (none) to 10 (very severe); for Question 6 (duration of morning stiffness), the response is from 0 (0 hours) to 10 (≥ 2 hours). The overall BASDAI score ranges from 0 to 10 cm. Lower scores indicate less disease activity. BASDAI50 is a 50% improvement from Baseline in BASDAI score.	Baseline and Weeks 52, 104, and 156

Collaborators and Investigators

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

Sponsor

AbbVie (prior sponsor, Abbott)

Investigators

- Study Director: Aileen L Pangan, MD, AbbVie

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.

- van der Heijde D, Sieper J, Maksymowych WP, Lambert RG, Chen S, Hojnik M, Anderson JK, Pangan AL. Clinical and MRI remission in patients with nonradiographic axial spondyloarthritis who received long-term open-label adalimumab treatment: 3-year results of the ABILITY-1 trial. Arthritis Res Ther. 2018 Mar 27;20(1):61. doi: 10.1186/s13075-018-1556-5.
- van der Heijde D, Sieper J, Maksymowych WP, Brown MA, Lambert RG, Rathmann SS, Pangan AL. Spinal inflammation in the absence of sacroiliac joint inflammation on magnetic resonance imaging in patients with active nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2014 Mar;66(3):667-73. doi: 10.1002/art.38283.
- Sieper J, van der Heijde D, Dougados M, Mease PJ, Maksymowych WP, Brown MA, Arora V, Pangan AL. Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis: results of a randomised placebo-controlled trial (ABILITY-1). Ann Rheum Dis. 2013 Jun;72(6):815-22. doi: 10.1136/annrheumdis-2012-201766. Epub 2012 Jul 7.

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.

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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		Results Reporting Dates		Study Record Updates	
First Submitted	2009-07-10	Results First Submitted	2012-02-02	Last Update Submitted that Met QC Criteria	2014-09-04
First Submitted that Met QC Criteria	2009-07-13	Results First Submitted that Met QC Criteria	2012-02-02	Last Update Posted (Estimated)	2014-09-09
First Posted (Estimated)	2009-07-14	Results First Posted (Estimated)	2012-03-06	Last Verified	2014-09

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Record History

Expand all / Collapse all

Terms related to this study

Additional Relevant MeSH Terms

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

Drug and device information, study documents, and helpful links

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

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Terms related to this study

Additional Relevant MeSH Terms

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

Drug and device information, study documents, and helpful links

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

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