Infliximab for Treatment of Axial Spondyloarthritis (P05336 AM1) (INFAST)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00844805

First received: February 13, 2009
Last updated: February 24, 2015
Last verified: February 2015
History of Changes

Purpose

The primary objective of this study was to assess the proportion of participants in the infliximab plus naproxen arm versus the placebo plus naproxen arm, in a population of participants with moderate-to-severe active axial spondyloarthritis and disease duration of ≤3 years, who achieve the Assessment in Ankylosing Spondylitis (ASAS) partial remission criteria.

Condition	Intervention	Phase
Ankylosing Spondylitis Axial Spondyloarthritis	Drug: Infliximab Drug: Placebo Drug: Naproxen	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Infliximab as First Line Therapy in Patients With Early Active Axial Spondyloarthritis Trial

Resource links provided by NLM:

Genetics Home Reference related topics: ankylosing spondylitis

MedlinePlus related topics: Ankylosing Spondylitis

Drug Information available for: Naproxen Naproxen sodium Infliximab

Genetic and Rare Diseases Information Center resources: Spondylarthropathy

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants Achieving the Assessment in Ankylosing Spondylitis (ASAS) Partial Remission Criteria at Week 28 [Time Frame: Week 28] [Designated as safety issue: No]

  ASAS domains were measured on a visual analog scale (VAS) of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

Secondary Outcome Measures:

- Number of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Follow-Up Phase [Time Frame: Week 52] [Designated as safety issue: No]

  ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

- Percentage of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Treatment Phase [Time Frame: Week 52] [Designated as safety issue: No]

  ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

- Change From Baseline of Berlin Magnetic Resonance Imaging (MRI) Spine Overall Score at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and short tau inversion recovery [STIR] for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.

- Change From Baseline in the Sacroiliac Overall Score at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.

- Change From Baseline of Berlin MRI Spine Overall Score at Week 52 [Time Frame: Baseline, Week 52] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.

- Change From Baseline in the Sacroiliac Overall Score at Week 52 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 28 [Time Frame: Week 28] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 28 [Time Frame: Week 28] [Designated as safety issue: No]

  Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions at the

sacroiliac joints was defined as a Score = 0.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 28 [Time Frame: Week 28] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0. Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 52 [Time Frame: Week 52] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 52 [Time Frame: Week 52] [Designated as safety issue: No]

  EaEach sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.

- Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 52 [Time Frame: Week 52] [Designated as safety issue: No]

  MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active spinal inflammatory lesions was defined as a Berlin MRI Score = 0. Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.

- Median Duration of Maintaining ASAS Partial Remission in the Follow-Up Phase [Time Frame: Week 52] [Designated as safety issue: No]

  ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

- Number of Participants Who Achieved ASAS Partial Remission That Experienced Disease Flare With Naproxen Maintenance Treatment in the Follow-Up Phase [Time Frame: Week 52] [Designated as safety issue: No]

  The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) employs a VAS of 0mm (best) to 100mm (worst). Disease flare was defined as reaching a BASDAI of ≥30 mm during two consecutive visits after Week 28 until Week 52. ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS partial remission criteria was defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

- Percentage of Participants That Achieved ASAS-40 Response at Week 28 in the Treatment Phase [Time Frame: Week 28] [Designated as safety issue: No]

  ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS-40 response was defined as ASAS achieving ≥40% improvement in 3 of the 4 domains (patient global assessment, total back pain, function, and inflammation), with an absolute improvement of ≥20 mm and no deterioration in the remaining domain.

- Percentage of Participants That Achieved ASAS-20 Response at Week 28 in the Treatment Phase [Time Frame: Week 28] [Designated as safety issue: No]

  ASAS-20 response was defined as ≥20% improvement in response according to following criteria: • An improvement of ≥20% from baseline and an absolute improvement from baseline of ≥10 mm in at least 3 of the following 4 domains (patient global assessment, pain, function,and

inflammation) • Absence of deterioration from baseline (≥20% and an absolute change of ≥10 mm) in the potential remaining domain.

Enrollment:	158
Study Start Date:	September 2009
Study Completion Date:	September 2011
Primary Completion Date:	April 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab + Naproxen Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.	Drug: Infliximab Other Names: • Remicade • SCH 215596 Drug: Naproxen Other Name: Naprosyn
Placebo Comparator: Placebo + Naproxen Placebo administered intravenously on Day 1 at Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.	Drug: Placebo Drug: Naproxen Other Name: Naprosyn
Experimental: Naproxen Only (Follow-Up) For participants who achieved partial remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.	Drug: Naproxen Other Name: Naprosyn
No Intervention: No Treatment (Follow-Up) For participants who achieved partial remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.	

Detailed Description:

In the 28-week treatment phase, participants were randomized to receive either infliximab plus naproxen or placebo plus naproxen.

After 28-weeks of treatment, participants that achieved partial remission in the treatment phase were randomized to continued treatment with naproxen or to receive no treatment and were followed for an additional 24 weeks (follow-up phase).

Eligibility

Ages Eligible for Study:	18 Years to 48 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Participant must:

- be 18 to 48 years of age
- have diagnosis of active axial spondyloarthritis, with disease duration of less than or equal to 3 years.
- have active disease during trial enrollment
- have limited treatment history for axial spondyloarthritis (must meet certain criteria)
- agree to an acceptable method of contraception (for women of childbearing potential and all men)
- must meet certain tuberculosis screening requirements
- must meet certain laboratory screening safety requirements
- have an x-ray of the sacroiliac joints available from within the previous 12 months (or have one performed during the Screening visit if site is outside of Germany).

Exclusion Criteria:

Participant will be excluded:

- for certain medical conditions and/or recent history of certain medical disorders
- for current or recent treatment with certain other medications and certain vaccinations.
- for being a woman who is breastfeeding, pregnant, or intending to become pregnant.
- if known to have had a substance abuse problem within the previous 3 years prior to screening.
- if currently participating in any other clinical study.
- for other administrative reasons.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Sieper J, Lenaerts J, Wollenhaupt J, Rudwaleit M, Mazurov VI, Myasoutova L, Park S, Song Y, Yao R, Chitkara D, Vastesaeger N; All INFAST Investigators. Efficacy and safety of infliximab plus naproxen versus naproxen alone in patients with early, active axial spondyloarthritis: results from the double-blind, placebo-controlled INFAST study, Part 1. Ann Rheum Dis. 2014 Jan;73(1):101-7. doi: 10.1136/annrheumdis-2012-203201. Epub 2013 May 21.

Sieper J, Lenaerts J, Wollenhaupt J, Rudwaleit M, Mazurov VI, Myasoutova L, Park S, Song Y, Yao R, Chitkara D, Vastesaeger N; All INFAST Investigators. Maintenance of biologic-free remission with naproxen or no treatment in patients with early, active axial spondyloarthritis: results from a 6-month, randomised, open-label follow-up study, INFAST Part 2. Ann Rheum Dis. 2014 Jan;73(1):108-13. doi: 10.1136/annrheumdis-2013-203460. Epub 2013 Jun 5.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00844805 History of Changes
Other Study ID Numbers:	P05336 2008-000982-51
Study First Received:	February 13, 2009
Results First Received:	September 20, 2012
Last Updated:	February 24, 2015
Health Authority:	United States: Institutional Review Board

Additional relevant MeSH terms:

Spondylarthritis	Analgesics, Non-Narcotic
Spondylitis	Anti-Inflammatory Agents
Spondylitis, Ankylosing	Anti-Inflammatory Agents, Non-Steroidal
Ankylosis	Antirheumatic Agents
Arthritis	Central Nervous System Agents
Bone Diseases	Cyclooxygenase Inhibitors
Bone Diseases, Infectious	Dermatologic Agents
Infection	Enzyme Inhibitors
Joint Diseases	Gastrointestinal Agents
Musculoskeletal Diseases	Gout Suppressants
Spinal Diseases	Molecular Mechanisms of Pharmacological Action
Spondylarthropathies	Peripheral Nervous System Agents
Infliximab	Pharmacologic Actions
Naproxen	Physiological Effects of Drugs
Analgesics	Sensory System Agents

ClinicalTrials.gov processed this record on April 10, 2016

TO TOP

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ClinicalTrials.gov Identifier:
NCT00844805

First received: February 13, 2009
Last updated: February 24, 2015
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History of Changes

Results First Received: September 20, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Ankylosing Spondylitis Axial Spondyloarthritis
Interventions:	Drug: Infliximab Drug: Placebo Drug: Naproxen

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.
Naproxen	For participants who achieved partial remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved partial remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Participant Flow for 2 periods

Period 1: Treatment Phase

	Infliximab + Naproxen	Placebo + Naproxen	Naproxen	No Treatment
STARTED	106	52	0	0
COMPLETED	96	45	0	0
NOT COMPLETED	10	7	0	0
Adverse Event	5	1	0	0
Withdrawal by Subject	3	4	0	0
Noncompliance With Protocol	1	0	0	0
Did Not Meet Protocol Eligibility	1	2	0	0

Period 2: Follow-Up Phase

	Infliximab + Naproxen	Placebo + Naproxen	Naproxen	No Treatment
STARTED	0	0	41 [1]	41 [1]
COMPLETED	0	0	32	32
NOT COMPLETED	0	0	9	9
Adverse Event	0	0	1	0
Withdrawal by Subject	0	0	6	3
Noncompliance With Protocol	0	0	0	1
Relapse/Recurrence	0	0	2	4
Did Not Meet Protocol Eligibility	0	0	0	1

[1] Participants who met partial remission criteria at the end of treatment entered the Follow-Up Phase.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.
Total	Total of all reporting groups

Baseline Measures

	Infliximab + Naproxen	Placebo + Naproxen	Total
Number of Participants [units: participants]	**105**	**51**	**156**
Age [1] [units: years] Mean (Standard Deviation)	**31.7 (8.51)**	**30.7 (7.34)**	**31.4 (8.12)**
Gender [2] [units: Participants]			
Female	**33**	**11**	**44**
Male	**72**	**40**	**112**

[1] Mean age presented is based on the Intent-to-Treat (ITT) population which consisted of participants treated with Infliximab + Naproxen (n=105) and participants treated with Placebo + Naproxen (n=51).

[2] Gender is based on the Intent-to-Treat (ITT) population which consisted of participants treated with Infliximab + Naproxen (n=105) and participants treated with Placebo + Naproxen (n=51).

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Achieving the Assessment in Ankylosing Spondylitis (ASAS) Partial Remission Criteria at Week 28 [Time Frame: Week 28]

Measure Type	Primary
Measure Title	Number of Participants Achieving the Assessment in Ankylosing Spondylitis (ASAS) Partial Remission Criteria at Week 28
Measure Description	ASAS domains were measured on a visual analog scale (VAS) of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	Placebo + Naproxen
Number of Participants Analyzed [units: participants]	**105**	**51**
Number of Participants Achieving the Assessment in Ankylosing Spondylitis (ASAS) Partial Remission Criteria at Week 28 [units: Participants]		
Achieved Partial Remission	**65**	**18**
Did Not Achieve Partial Remission	**40**	**33**

No statistical analysis provided for Number of Participants Achieving the Assessment in Ankylosing Spondylitis (ASAS) Partial Remission Criteria at Week 28

2. Secondary: Number of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Follow-Up Phase [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Number of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Follow-Up Phase
Measure Description	ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.

No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	No Treatment
Number of Participants Analyzed [units: participants]	**40**	**40**
Number of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Follow-Up Phase [units: Participants]		
Achieved Partial Remission	**19**	**16**
Did Not Achieve Partial Remission	**21**	**24**

No statistical analysis provided for Number of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Follow-Up Phase

3. Secondary: Percentage of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Treatment Phase [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Treatment Phase
Measure Description	ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worst situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	Placebo + Naproxen
Number of Participants Analyzed	**105**	**51**

[units: participants]		
Percentage of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Treatment Phase [units: Percentage of Participants]	**40**	**55**

No statistical analysis provided for Percentage of Participants Maintaining the ASAS Partial Remission Criteria at Week 52 By Treatment Assignment in the Treatment Phase

4. Secondary: Change From Baseline of Berlin Magnetic Resonance Imaging (MRI) Spine Overall Score at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline of Berlin Magnetic Resonance Imaging (MRI) Spine Overall Score at Week 28
Measure Description	MRI scans (T1 for chronic changes and short tau inversion recovery [STIR] for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The number of participants represented those with a screening value and a value at treatment Week 28.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**98**	**47**
Change From Baseline of Berlin Magnetic Resonance Imaging (MRI) Spine Overall Score at Week 28 [units: Units on a Scale] Median (Inter-Quartile Range)	**-0.5 (-3.5 to 0.0)**	**0.0 (-4.7 to 0.0)**

No statistical analysis provided for Change From Baseline of Berlin Magnetic Resonance Imaging (MRI) Spine Overall Score at Week 28

5. Secondary: Change From Baseline in the Sacroiliac Overall Score at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in the Sacroiliac Overall Score at Week 28
Measure Description	Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The number of participants represented those with a screening value and a value at treatment Week 28.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**97**	**47**
Change From Baseline in the Sacroiliac Overall Score at Week 28 [units: Units on a Scale] Median (Inter-Quartile Range)	**-2.0 (-7.0 to -0.5)**	**-3.0 (-6.5 to -1.0)**

No statistical analysis provided for Change From Baseline in the Sacroiliac Overall Score at Week 28

6. Secondary: Change From Baseline of Berlin MRI Spine Overall Score at Week 52 [Time Frame: Baseline, Week 52]

Measure Type	Secondary
Measure Title	Change From Baseline of Berlin MRI Spine Overall Score at Week 52
Measure Description	MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.
Time Frame	Baseline, Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The number of participants represents those with a Week 28 values and those with a Week 52 value.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**
Number of Participants Analyzed [units: participants]	**37**	**37**
Change From Baseline of Berlin MRI Spine Overall Score at Week 52 [units: Units on a Scale] Median (Inter-Quartile Range)	**0.0 (0.0 to 1.0)**	**0.0 (0.0 to 2.3)**

No statistical analysis provided for Change From Baseline of Berlin MRI Spine Overall Score at Week 52

7. Secondary: Change From Baseline in the Sacroiliac Overall Score at Week 52 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in the Sacroiliac Overall Score at Week 52
Measure Description	Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The number of participants represented those with a screening value and a value at treatment Week 28.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**

Number of Participants Analyzed [units: participants]	**36**	**36**
Change From Baseline in the Sacroiliac Overall Score at Week 52 [units: Units on a Scale] Median (Inter-Quartile Range)	**1.1 (0.0 to 4.0)**	**1.0 (0.0 to 3.3)**

No statistical analysis provided for Change From Baseline in the Sacroiliac Overall Score at Week 52

8. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 28 [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 28
Measure Description	MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**105**	**51**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 28 [units: Participants]	**63**	**23**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 28

Groups [1]	All groups

Method [2]	Fisher Exact
P Value [3]	=0.0884
Difference in Percentages [4]	14.9
95% Confidence Interval	-1.7 to 31.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

9. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 28 [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 28
Measure Description	Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions at the sacroiliac joints was defined as a Score = 0.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**

Number of Participants Analyzed [units: participants]	**105**	**51**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 28 [units: Participants]	**29**	**3**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 28

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.0013
Difference in Percentages [4]	21.7
95% Confidence Interval	11.0 to 32.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

10. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 28 [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 28
Measure Description	MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0. Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**105**	**51**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 28 [units: Participants]	**19**	**0**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 28

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.0004
Difference in Percentages [4]	18.1
95% Confidence Interval	10.7 to 25.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

11. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 52 [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 52
Measure Description	MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active inflammatory lesions was defined as a Berlin MRI Score = 0.
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants that were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**
Number of Participants Analyzed [units: participants]	**40**	**40**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 52 [units: Participants]	**20**	**16**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine at Treatment Week 52

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.5005
Difference in Percentages [4]	10.0
95% Confidence Interval	-11.7 to 31.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical

	significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

12. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 52 [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 52
Measure Description	EaEach sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**
Number of Participants Analyzed [units: participants]	**40**	**40**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 52 [units: Participants]	**3**	**4**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Sacroiliac Joint at Treatment Week 52

Groups [1]	All groups
[2]	Fisher Exact

Method	
P Value [3]	=1.0000
Difference in Percentages [4]	-2.5
95% Confidence Interval	-14.9 to 9.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

13. Secondary: Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 52 [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 52
Measure Description	MRI scans (T1 for chronic changes and STIR for active changes) of the whole spine was performed to determine the Berlin MRI Spine Score. The Berlin MRI scoring for the spine was assessed on a scale of 0 (best) to 3 (worst) for a maximum total score of 69, with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active spinal inflammatory lesions was defined as a Berlin MRI Score = 0. Each sacroiliac joint was divided into four quadrants. An activity score of 0 (best) to 3 (worst) was assessed for every quadrant of the left and right sacroiliac joint separately for a total maximum score of 24, with with 0 = no inflammatory lesions; 1 = minor bone marrow edema; 2 = moderate bone marrow edema; 3 = major bone marrow edema; or N = non readable. Complete absence of active sacroiliac inflammatory lesions was defined as a Score = 0.
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in

	the follow-up phase.

Measured Values

	Naproxen	No Treatment
Number of Participants Analyzed [units: participants]	**40**	**40**
Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 52 [units: Participants]	**1**	**1**

Statistical Analysis 1 for Number of Participants With Complete Absence of Active Inflammatory Lesions at the Spine and Sacroiliac Joint at Treatment Week 52

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=1.0000
Difference in Percentages [4]	0.0
95% Confidence Interval	-6.8 to 6.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

14. Secondary: Median Duration of Maintaining ASAS Partial Remission in the Follow-Up Phase [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Median Duration of Maintaining ASAS Partial Remission in the Follow-Up Phase
Measure Description	ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS partial remission criteria is defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized to treatment, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**
Number of Participants Analyzed [units: participants]	**40**	**40**
Median Duration of Maintaining ASAS Partial Remission in the Follow-Up Phase [units: Weeks] Median (Full Range)	**23.00 (3.43 to 26.71)**	**12.57 (4.71 to 25.14)**

Statistical Analysis 1 for Median Duration of Maintaining ASAS Partial Remission in the Follow-Up Phase

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	=0.3802

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

15. Secondary: Number of Participants Who Achieved ASAS Partial Remission That Experienced Disease Flare With Naproxen Maintenance Treatment in the Follow-Up Phase [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved ASAS Partial Remission That Experienced Disease Flare With Naproxen Maintenance Treatment in the Follow-Up Phase
Measure Description	The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) employs a VAS of 0mm (best) to 100mm (worst). Disease flare was defined as reaching a BASDAI of ≥30 mm during two consecutive visits after Week 28 until Week 52. ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS partial remission criteria was defined as reaching ≤20 mm in all 4 ASAS domains (i.e., patient global assessment, total back pain, function, and inflammation).

Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all subjects who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Measured Values

	Naproxen	**No Treatment**
Number of Participants Analyzed [units: participants]	**40**	**40**
Number of Participants Who Achieved ASAS Partial Remission That Experienced Disease Flare With Naproxen Maintenance Treatment in the Follow-Up Phase [units: Participants]	**1**	**3**

Statistical Analysis 1 for Number of Participants Who Achieved ASAS Partial Remission That Experienced Disease Flare With Naproxen Maintenance Treatment in the Follow-Up Phase

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.6153
Difference in Percentages [4]	-5.0
95% Confidence Interval	-14.5 to 4.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

16. Secondary: Percentage of Participants That Achieved ASAS-40 Response at Week 28 in the Treatment Phase [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Percentage of Participants That Achieved ASAS-40 Response at Week 28 in the Treatment Phase
Measure Description	ASAS domains were measured on a VAS of 0 to 100 mm (with 0 being the very best situation and 100 being the very worse situation). ASAS-40 response was defined as ASAS achieving ≥40% improvement in 3 of the 4 domains (patient global assessment, total back pain, function, and inflammation), with an absolute improvement of ≥20 mm and no deterioration in the remaining domain.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**105**	**51**
Percentage of Participants That Achieved ASAS-40 Response at Week 28 in the Treatment Phase [units: Percentage of Participants]	**79**	**29**

Statistical Analysis 1 for Percentage of Participants That Achieved ASAS-40 Response at Week 28 in the Treatment Phase

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.0263
Difference in Percentages [4]	18.4
95% Confidence Interval	2.5 to 34.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

17. Secondary: Percentage of Participants That Achieved ASAS-20 Response at Week 28 in the Treatment Phase [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Percentage of Participants That Achieved ASAS-20 Response at Week 28 in the Treatment Phase
Measure Description	ASAS-20 response was defined as ≥20% improvement in response according to following criteria: • An improvement of ≥20% from baseline and an absolute improvement from baseline of ≥10 mm in at least 3 of the following 4 domains (patient global assessment, pain, function,and inflammation) • Absence of deterioration from baseline (≥20% and an absolute change of ≥10 mm) in the potential remaining domain.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat Population consisted of all participants who were randomized, took at least one dose of study medication, and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.

Measured Values

	Infliximab + Naproxen	**Placebo + Naproxen**
Number of Participants Analyzed [units: participants]	**105**	**51**
Percentage of Participants That Achieved ASAS-20 Response at Week 28 in the Treatment Phase [units: Percentage of Participants]	**85**	**37**

Statistical Analysis 1 for Percentage of Participants That Achieved ASAS-20 Response at Week 28 in the Treatment Phase

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	=0.3011
Difference in Percentages [4]	8.4
95% Confidence Interval	-6.0 to 22.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The 95% CI for treatment differences were computed using Wilson's Method.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to Week 52.
Additional Description	The Safety Population consisted of all participants who received at least one dose of study medication.

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of 1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Serious Adverse Events

	Infliximab + Naproxen	**Placebo + Naproxen**	**Naproxen**	**No Treatment**
Total, serious adverse events				
# participants affected / at risk	**6/105 (5.71%)**	**3/52 (5.77%)**	**0/41 (0.00%)**	**3/41 (7.32%)**
Blood and lymphatic system disorders				

Anaemia † 1				
# participants affected / at risk	**0/105 (0.00%)**	**1/52 (1.92%)**	**0/41 (0.00%)**	**1/41 (2.44%)**
# events	**0**	**1**	**0**	**1**
General disorders				
Chest Discomfort † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Infections and infestations				
Pneumonia † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Tuberculosis † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Investigations				
Hepatic Enzyme Increased † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Musculoskeletal and connective tissue disorders				
Ankylosing Spondylitis † 1				
# participants affected / at risk	**0/105 (0.00%)**	**1/52 (1.92%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**0**	**1**	**0**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Breast Cancer † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Carcinoma In Situ † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**1/41 (2.44%)**
# events	**1**	**0**	**0**	**1**
Nervous system disorders				
Dizziness † 1				
# participants affected / at risk	**1/105 (0.95%)**	**0/0**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**1**	**0**	**0**	**0**
Pregnancy, puerperium and perinatal conditions				
Foetal Distress Syndrome † 1				
			0/41 (0.00%)	

# participants affected / at risk	1/105 (0.95%)	0/52 (0.00%)		0/41 (0.00%)
# events	1	0	0	0
Pregnancy † 1				
# participants affected / at risk	1/105 (0.95%)	0/52 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
# events	1	0	0	0
Uterine Hypotonus † 1				
# participants affected / at risk	1/105 (0.95%)	0/52 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
# events	1	0	0	0
Reproductive system and breast disorders				
Ovarian Cyst Ruptured † 1				
# participants affected / at risk	0/105 (0.00%)	1/52 (1.92%)	0/41 (0.00%)	1/41 (2.44%)
# events	0	1	0	1
Respiratory, thoracic and mediastinal disorders				
Dyspnoea † 1				
# participants affected / at risk	1/105 (0.95%)	0/52 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
# events	1	0	0	0
Skin and subcutaneous tissue disorders				
Dermatitis Atopic † 1				
# participants affected / at risk	0/105 (0.00%)	1/52 (1.92%)	0/41 (0.00%)	1/41 (2.44%)
# events	0	1	0	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to Week 52.
Additional Description	The Safety Population consisted of all participants who received at least one dose of study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Infliximab + Naproxen	Infliximab administered at a dose of 5 mg/kg intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks during the 28-week treatment phase.
Placebo + Naproxen	Placebo administered intravenously on Day 1 of Weeks 0, 2, 6, 12, 18, and 24, combined with naproxen administered at a daily dose of 1000 mg for 28 weeks, during the 28-week treatment phase.
Naproxen	For participants who achieved remission during 28-week treatment phase, naproxen was continued at a daily dose of

	1000 mg administered orally for an additional 24 weeks in the follow-up phase.
No Treatment	For participants who achieved remission during Treatment phase, no treatment was administered for an additional 24 weeks in the follow-up phase.

Other Adverse Events

	Infliximab + Naproxen	Placebo + Naproxen	Naproxen	No Treatment
Total, other (not including serious) adverse events				
# participants affected / at risk	**24/105 (22.86%)**	**8/52 (15.38%)**	**6/41 (14.63%)**	**11/41 (26.83%)**
Gastrointestinal disorders				
Abdominal Pain Upper † 1				
# participants affected / at risk	**8/105 (7.62%)**	**2/52 (3.85%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**10**	**2**	**0**	**0**
Dyspepsia † 1				
# participants affected / at risk	**3/105 (2.86%)**	**3/52 (5.77%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**3**	**7**	**0**	**0**
Diarrhoea † 1				
# participants affected / at risk	**0/105 (0.00%)**	**0/52 (0.00%)**	**3/41 (7.32%)**	**1/41 (2.44%)**
# events	**0**	**0**	**4**	**3**
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	**13/105 (12.38%)**	**5/52 (9.62%)**	**4/41 (9.76%)**	**6/41 (14.63%)**
# events	**16**	**5**	**4**	**9**
Bronchitis † 1				
# participants affected / at risk	**0/105 (0.00%)**	**0/52 (0.00%)**	**0/41 (0.00%)**	**4/41 (9.76%)**
# events	**0**	**0**	**0**	**5**
Rhinitis † 1				
# participants affected / at risk	**0/105 (0.00%)**	**0/52 (0.00%)**	**3/41 (7.32%)**	**2/41 (4.88%)**
# events	**0**	**0**	**3**	**2**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**7/105 (6.67%)**	**2/52 (3.85%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
# events	**14**	**5**	**0**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The investigator agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media. The sponsor shall have the right to review and comment with respect to data analysis and presentation with regard to protected proprietary information, data accuracy, and fair balance.

Results Point of Contact:

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Publications of Results:

Sieper J, Lenaerts J, Wollenhaupt J, Rudwaleit M, Mazurov VI, Myasoutova L, Park S, Song Y, Yao R, Chitkara D, Vastesaeger N; All INFAST Investigators. Efficacy and safety of infliximab plus naproxen versus naproxen alone in patients with early, active axial spondyloarthritis: results from the double-blind, placebo-controlled INFAST study, Part 1. Ann Rheum Dis. 2014 Jan;73(1):101-7. doi: 10.1136/annrheumdis-2012-203201. Epub 2013 May 21.

Sieper J, Lenaerts J, Wollenhaupt J, Rudwaleit M, Mazurov VI, Myasoutova L, Park S, Song Y, Yao R, Chitkara D, Vastesaeger N; All INFAST Investigators. Maintenance of biologic-free remission with naproxen or no treatment in patients with early, active axial spondyloarthritis: results from a 6-month, randomised, open-label follow-up study, INFAST Part 2. Ann Rheum Dis. 2014 Jan;73(1):108-13. doi: 10.1136/annrheumdis-2013-203460. Epub 2013 Jun 5.

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TO TOP

For Patients and Families | For Researchers | For Study Record Managers