A Study to Evaluate the Switch From Etanercept to Infliximab in Subjects With Moderate-to-Severe Psoriasis (Study P05133) (TANGO)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Centocor, Inc.

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

ClinicalTrials.gov Identifier:
NCT00686595

First received: May 27, 2008
Last updated: February 19, 2016
Last verified: February 2016
History of Changes

Purpose

This study will evaluate the efficacy, tolerability, and effect on the quality of life of infliximab in adults with moderate-to-severe psoriasis who are resistant to etanercept after 12 weeks of treatment or have failed 24 weeks of treatment with etanercept. Infliximab will be administered as an intravenous infusion of 5 mg/kg at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Condition	Intervention	Phase
Psoriasis	Biological: Infliximab	Phase 4

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: swiTching From etAnercept to iNfliximab in the Treatment of Moderate to Severe Psoriasis; a Multi-center, Open Label Trial evaluatinG the Efficacy, tOlerance and Safety (TANGO)

Resource links provided by NLM:

MedlinePlus related topics: Psoriasis

Drug Information available for: Infliximab

U.S. FDA Resources

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

Primary Outcome Measures:

- Psoriasis Area and Severity Index (PASI) 75 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 10 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 10.

Secondary Outcome Measures:

- PASI 75 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 18 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 18.

- PASI 75 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 24 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 24.

- PASI 50 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 10 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 10.

- PASI 50 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 18 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 18.

- PASI 50 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 24 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 24.

- PASI 90 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 10 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 10.

- PASI 90 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 18 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 18.

- PASI 90 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 24 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 24.in PASI at Week 24

- PASI 100 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 10 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 10.

- PASI 100 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 18 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 18.

- PASI 100 Response Rate at Week 24 [Time Frame: 24 weeks] [Designated as safety issue: No]

  PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 24 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 24.

- Percent Reduction in Self-Administered Psoriasis Area Severity Index (SAPASI) at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  SAPASI is the participant's measurement of severity of psoriasis. The participant estimates the area of psoriatic involvement for each body district (head, upper limbs, trunk and lower limbs) and scores it from 0 (no involvement)-6 (90-100% involvement); and the extent of psoriasis from 0 (no involvement) to 4 (very marked) for each - erythema, desquamation and induration of the plaques. The final score computed by the investigator ranged from 0-72. The percent reduction in SAPASI at Week 18 compared to baseline is reported.

- Percent Reduction in SAPASI at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  SAPASI is the participant's measurement of severity of psoriasis. The participant estimates the area of psoriatic involvement for each body district (head, upper limbs, trunk and lower limbs) and scores it from 0 (no involvement)-6 (90-100% involvement); and the extent of psoriasis from 0 (no involvement) to 4 (very marked) for each - erythema, desquamation and induration of the plaques. The final score computed by the investigator ranged from 0-72. The percent reduction in SAPASI at Week 24 compared to baseline is reported.

- Percent Reduction in Affected Body Surface Area (BSA) at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  The BSA is the physician's evaluation for the extent of disease. The entire body area is divided into 4 districts: head, upper limbs, trunk and lower limbs to which corresponds the 10%, 20%, 30% and 40% of the entire body surface respectively. The investigator assesses the percentage of the participant's body surface area affected by psoriasis in each district. The final affected BSA value is the sum of the percentage of each district. The percent reduction in affected BSA at Week 18 compared to baseline is reported.

- Percent Reduction in Affected BSA at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  The BSA is the physician's evaluation for the extent of disease. The entire body area is divided into 4 districts: head, upper limbs, trunk and lower limbs to which corresponds the 10%, 20%, 30% and 40% of the entire body surface respectively. The investigator assesses the percentage of the participant's body surface area affected by psoriasis in each district. The final affected BSA value is the sum of the percentage of each district. The percent reduction in affected BSA at Week 24 compared to baseline is reported.

- Percent Reduction in Visual Analogue Scale (VAS) Referred Itch at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  VAS was used to measure itch. Participants reported itch using VAS - a line ranging from 0 cm to 10 cm, measured by the investigator. 0 cm referred to absence of itch and 10 cm referred to severe itching. The percent reduction in VAS at Week 18 compared to baseline is reported.

- Percent Reduction in VAS Referred Itch at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  VAS was used to measure itch. Participants reported itch using VAS - a line ranging from 0 cm to 10 cm, measured by the investigator. 0 cm referred to absence of itch and 10 cm referred to severe itching. The percent reduction in VAS at Week 24 compared to baseline is reported.

- Percent Reduction in Dermatology Life Quality Index (DLQI) Total Score at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  DLQI total score comprises 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. DLQI total scores range from 0 to 30, with 0 corresponding to the best quality of life and 30

to the worst. The percent reduction in DLQI score at Week 18 compared to baseline is reported.

- Percent Reduction in DLQI Total Score at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  DLQI total score comprises 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. DLQI total scores range from 0 to 30, with 0 corresponding to the best quality of life and 30 to the worst. The percent reduction in DLQI score at Week 24 compared to baseline is reported.

- Percent Reduction in Skin Index Questionnaire (SKINDEX-29) Score at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  The SKINDEX-29 measures the quality of life in dermatological participants, who complete a questionnaire assessing 3 scales - burden of symptoms, social functioning and emotional state. Participants answered 29 questions referring to the previous 4-week period, on a 5-point scale from "never" (=0) to "all the time" (=4). The score for each scale ranges from 0 to 100 and higher scores reflect a worse quality of life. The percent reduction in SKINDEX-29 scores at Week 18 compared to baseline is reported.

- Percent Reduction in SKINDEX-29 Scores at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  The SKINDEX-29 measures the quality of life in dermatological participants, who complete a questionnaire assessing 3 scales - burden of symptoms, social functioning and emotional state. Participants answered 29 questions referring to the previous 4-week period, on a 5-point scale from "never" (=0) to "all the time" (=4). The score for each scale ranges from 0 to 100 and higher scores reflect a worse quality of life. The percent reduction in SKINDEX-29 scores at Week 24 compared to baseline is reported.

Enrollment:	48
Study Start Date:	October 2007
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab 5 mg/kg Infliximab 5 mg/kg intravenous (IV) infusion administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).	Biological: Infliximab Infliximab 5 mg/kg IV infusion. Other Name: Remicade, SCH 215596

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- >=18 to 75 years of age at Screening, either sex, and any race.
- Diagnosis of moderate-to-severe plaque psoriasis >6 months prior to Screening.
- Resistant (after 12 weeks) or failed 24 weeks of etanercept treatment.
- Not reached PASI 75 at Screening Visit after 24 weeks of etanercept treatment or resistant to etanercept.
- Agree to avoid prolonged sun exposure or artificial ultraviolet light sources during study.
- Satisfy requirements of Screening and tuberculosis (TB) test as specified in protocol.
- Chest x-ray at Visit 1 or within 3 months prior to Visit 1 with no evidence of malignancy, infection, or fibrosis.
- Laboratory tests must be within protocol-specified parameters.
- Free of any clinically significant disease that would interfere with study evaluations.
- Willing to participate and adhere to study procedures by signing written informed consent.
- Women of childbearing potential and all men must be using adequate birth control measures and continue to do so until 6 months after receiving last dose of study medication.
- Females of childbearing potential must have negative serum pregnancy test at Visit 1 and negative urine pregnancy test at Visit 2.

Exclusion Criteria:

- Achieve PASI 75 or have BSA <10% after 24 weeks of etanercept.
- Current drug-induced psoriasis.
- Females who are pregnant or nursing and both males and females who are planning pregnancy during study period or during 6 months after receiving last dose of study medication.
- Previously treated with infliximab.
- Currently taking or have taken protocol-specified prohibited drugs within specified time frame prior to Baseline.
- Congestive Heart Failure (CHF)
- Chronic or recurrent infectious disease.
- Have or have had serious infection, or been hospitalized or received IV antibiotics for this infection during the 2 months prior to Visit 1.
- Have or have had opportunistic infection within 6 months prior to Visit 1.
- Have or have had herpes zoster infection within 2 months prior to Visit 1.
- Human Immunodeficiency Virus (HIV), hepatitis B or C.
- History of any clinically significant adverse events (AEs) to murine or chimeric proteins or human/murine recombinant products.
- Current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurological, cerebral, or psychiatric disease.
- History of demyelinating disease or symptoms suggestive of multiple sclerosis or optic neuritis.
- Current signs and symptoms or history of systemic lupus erythematosus.
- Transplanted organ (exception - corneal transplant >3 months prior to Visit 1).
- History of lymphoproliferative disease, including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location.
- Malignancy within previous 5 years (exception - basal cell carcinoma of skin that has been treated with no evidence of recurrence).
- Unable or unwilling to undergo multiple venipunctures because of poor tolerability or lack of easy access to veins.
- Have had substance abuse (drug or alcohol) problem within previous 3 years.
- History of any clinically significant adverse reactions (including allergic reactions) to paracetamol/acetaminophen or histamine H1 receptor antagonist.
- In a situation or have a condition that, in opinion of investigator, may interfere with optimal participation in study.
- Used investigational drugs within 4 weeks of Screening.
- Participating in any other clinical study.
- Staff personnel directly involved with this study.
- Family members of investigational study staff.

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

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00686595 History of Changes
Other Study ID Numbers:	P05133
Study First Received:	May 27, 2008
Results First Received:	January 27, 2011
Last Updated:	February 19, 2016
Health Authority:	Italy: Ministry of Health

Additional relevant MeSH terms:

Psoriasis	Central Nervous System Agents
Skin Diseases	Dermatologic Agents

Skin Diseases, Papulosquamous
Infliximab
Analgesics
Analgesics, Non-Narcotic
Anti-Inflammatory Agents
Anti-Inflammatory Agents, Non-Steroidal
Antirheumatic Agents
Gastrointestinal Agents
Peripheral Nervous System Agents
Pharmacologic Actions
Physiological Effects of Drugs
Sensory System Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on April 10, 2016

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A Study to Evaluate the Switch From Etanercept to Infliximab in Subjects With Moderate-to-Severe Psoriasis (Study P05133) (TANGO)

This study has been completed.

Sponsor:
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Collaborator:
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Information provided by (Responsible Party):
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ClinicalTrials.gov Identifier:
NCT00686595

First received: May 27, 2008
Last updated: February 19, 2016
Last verified: February 2016
History of Changes

Results First Received: January 27, 2011

Study Type:	Interventional
Study Design:	Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Psoriasis
Intervention:	Biological: Infliximab

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
48 participants were enrolled in this study. Of these, 38 participants received at least one dose of the study medication and represent the intent-to-treat (ITT) population.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Participant Flow: Overall Study

	Infliximab 5 mg/kg
STARTED	**38**
COMPLETED	**31**
NOT COMPLETED	**7**
Adverse Event	**3**
Protocol Violation	**1**
Lost to Follow-up	**1**
Lack of Efficacy	**1**
Poor Compliance	**1**

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 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Baseline Measures

	Infliximab 5 mg/kg
Number of Participants [units: participants]	**38**
Age [units: years] Mean (Standard Deviation)	**46.54 (9.70)**
Gender [units: participants]	
Female	**10**
Male	**28**

Outcome Measures

Hide All Outcome Measures

1. Primary: Psoriasis Area and Severity Index (PASI) 75 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks]

Measure Type	Primary
Measure Title	Psoriasis Area and Severity Index (PASI) 75 Response Rate at Week 10
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 10 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 10.
Time Frame	Baseline and 10 weeks
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.
Participants from the intent-to-treat (ITT) population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
Psoriasis Area and Severity Index (PASI) 75 Response Rate at Week 10 [units: Percentage of participants]	**71**

No statistical analysis provided for Psoriasis Area and Severity Index (PASI) 75 Response Rate at Week 10

2. Secondary: PASI 75 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks]

Measure Type	Secondary
Measure Title	PASI 75 Response Rate at Week 18
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 18 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 18.
Time Frame	Baseline and 18 weeks

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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**32**
PASI 75 Response Rate at Week 18 [units: Percent of participants]	**94**

No statistical analysis provided for PASI 75 Response Rate at Week 18

3. Secondary: PASI 75 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks]

Measure Type	Secondary
Measure Title	PASI 75 Response Rate at Week 24
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 75 response rate at Week 24 is measured as the percentage of participants who achieved at least 75% improvement from baseline PASI at Week 24.
Time Frame	Baseline and 24 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	35
PASI 75 Response Rate at Week 24 [units: Percentage of participants]	74

No statistical analysis provided for PASI 75 Response Rate at Week 24

4. Secondary: PASI 50 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks]

Measure Type	Secondary
Measure Title	PASI 50 Response Rate at Week 10
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 10 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 10.
Time Frame	Baseline and 10 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	35
PASI 50 Response Rate at Week 10 [units: Percentage of participants]	91

No statistical analysis provided for PASI 50 Response Rate at Week 10

5. Secondary: PASI 50 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks]

Measure Type	Secondary

Measure Title	PASI 50 Response Rate at Week 18
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 18 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 18.
Time Frame	Baseline and 18 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**32**
PASI 50 Response Rate at Week 18 [units: Percentage of participants]	**97**

No statistical analysis provided for PASI 50 Response Rate at Week 18

6. Secondary: PASI 50 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks]

Measure Type	Secondary
Measure Title	PASI 50 Response Rate at Week 24
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 50 response rate at Week 24 is measured as the percentage of participants who achieved at least 50% improvement from baseline PASI at Week 24.
Time Frame	Baseline and 24 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
PASI 50 Response Rate at Week 24 [units: Percentage of participants]	**89**

No statistical analysis provided for PASI 50 Response Rate at Week 24

7. Secondary: PASI 90 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks]

Measure Type	Secondary
Measure Title	PASI 90 Response Rate at Week 10
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 10 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 10.
Time Frame	Baseline and 10 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
PASI 90 Response Rate at Week 10 [units: Percentage of participants]	**37**

No statistical analysis provided for PASI 90 Response Rate at Week 10

8. Secondary: PASI 90 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks]

Measure Type	Secondary
Measure Title	PASI 90 Response Rate at Week 18
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 18 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 18.
Time Frame	Baseline and 18 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**32**
PASI 90 Response Rate at Week 18 [units: Percentage of participants]	**56**

No statistical analysis provided for PASI 90 Response Rate at Week 18

9. Secondary: PASI 90 Response Rate at Week 24 [Time Frame: Baseline and 24 weeks]

Measure Type	Secondary
Measure Title	PASI 90 Response Rate at Week 24
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 90 response rate at Week 24 is measured as the percentage of participants who achieved at least 90% improvement from baseline PASI at Week 24.in PASI at Week 24
Time Frame	Baseline and 24 weeks

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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
PASI 90 Response Rate at Week 24 [units: Percentage of participants]	**54**

No statistical analysis provided for PASI 90 Response Rate at Week 24

10. Secondary: PASI 100 Response Rate at Week 10 [Time Frame: Baseline and 10 weeks]

Measure Type	Secondary
Measure Title	PASI 100 Response Rate at Week 10
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 10 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 10.
Time Frame	Baseline and 10 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	35
PASI 100 Response Rate at Week 10 [units: Percentage of participants]	17

No statistical analysis provided for PASI 100 Response Rate at Week 10

11. Secondary: PASI 100 Response Rate at Week 18 [Time Frame: Baseline and 18 weeks]

Measure Type	Secondary
Measure Title	PASI 100 Response Rate at Week 18
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 18 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 18.
Time Frame	Baseline and 18 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	32
PASI 100 Response Rate at Week 18 [units: Percentage of participants]	31

No statistical analysis provided for PASI 100 Response Rate at Week 18

12. Secondary: PASI 100 Response Rate at Week 24 [Time Frame: 24 weeks]

Measure Type	Secondary

Measure Title	PASI 100 Response Rate at Week 24
Measure Description	PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 24 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 24.
Time Frame	24 weeks
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.
Participants from the ITT population for whom the PASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
PASI 100 Response Rate at Week 24 [units: Percentage of participants]	**40**

No statistical analysis provided for PASI 100 Response Rate at Week 24

13. Secondary: Percent Reduction in Self-Administered Psoriasis Area Severity Index (SAPASI) at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Percent Reduction in Self-Administered Psoriasis Area Severity Index (SAPASI) at Week 18
Measure Description	SAPASI is the participant's measurement of severity of psoriasis. The participant estimates the area of psoriatic involvement for each body district (head, upper limbs, trunk and lower limbs) and scores it from 0 (no involvement)-6 (90-100% involvement); and the extent of psoriasis from 0 (no involvement) to 4 (very marked) for each - erythema, desquamation and induration of the plaques. The final score computed by the investigator ranged from 0-72. The percent reduction in SAPASI at Week 18 compared to baseline is reported.
Time Frame	Baseline and Week 18
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.
Participants from the ITT population for whom the SAPASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**31**
Percent Reduction in Self-Administered Psoriasis Area Severity Index (SAPASI) at Week 18 [units: Percent reduction] Mean (Standard Deviation)	**89 (15)**

No statistical analysis provided for Percent Reduction in Self-Administered Psoriasis Area Severity Index (SAPASI) at Week 18

14. Secondary: Percent Reduction in SAPASI at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Percent Reduction in SAPASI at Week 24
Measure Description	SAPASI is the participant's measurement of severity of psoriasis. The participant estimates the area of psoriatic involvement for each body district (head, upper limbs, trunk and lower limbs) and scores it from 0 (no involvement)-6 (90-100% involvement); and the extent of psoriasis from 0 (no involvement) to 4 (very marked) for each - erythema, desquamation and induration of the plaques. The final score computed by the investigator ranged from 0-72. The percent reduction in SAPASI at Week 24 compared to baseline is reported.
Time Frame	Baseline and Week 24
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.
Participants from the ITT population for whom the SAPASI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**33**
Percent Reduction in SAPASI at Week 24	

[units: Percent reduction] Mean (Standard Deviation)	**82 (29)**

No statistical analysis provided for Percent Reduction in SAPASI at Week 24

15. Secondary: Percent Reduction in Affected Body Surface Area (BSA) at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Percent Reduction in Affected Body Surface Area (BSA) at Week 18
Measure Description	The BSA is the physician's evaluation for the extent of disease. The entire body area is divided into 4 districts: head, upper limbs, trunk and lower limbs to which corresponds the 10%, 20%, 30% and 40% of the entire body surface respectively. The investigator assesses the percentage of the participant's body surface area affected by psoriasis in each district. The final affected BSA value is the sum of the percentage of each district. The percent reduction in affected BSA at Week 18 compared to baseline is reported.
Time Frame	Baseline and Week 18
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.
Participants from the ITT population for whom the BSA assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**32**
Percent Reduction in Affected Body Surface Area (BSA) at Week 18 [units: Percent reduction] Mean (Standard Deviation)	**82 (28)**

No statistical analysis provided for Percent Reduction in Affected Body Surface Area (BSA) at Week 18

16. Secondary: Percent Reduction in Affected BSA at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Percent Reduction in Affected BSA at Week 24
Measure Description	The BSA is the physician's evaluation for the extent of disease. The entire body area is divided into 4 districts: head, upper limbs, trunk and lower limbs to which corresponds the 10%, 20%, 30% and 40% of the entire body surface respectively. The investigator assesses the percentage of the participant's body surface area affected by psoriasis in

	each district. The final affected BSA value is the sum of the percentage of each district. The percent reduction in affected BSA at Week 24 compared to baseline is reported.
Time Frame	Baseline and Week 24
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.
Participants from the ITT population for whom the BSA assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**35**
Percent Reduction in Affected BSA at Week 24 [units: Percent reduction] Mean (Standard Deviation)	**72 (39)**

No statistical analysis provided for Percent Reduction in Affected BSA at Week 24

17. Secondary: Percent Reduction in Visual Analogue Scale (VAS) Referred Itch at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Percent Reduction in Visual Analogue Scale (VAS) Referred Itch at Week 18
Measure Description	VAS was used to measure itch. Participants reported itch using VAS - a line ranging from 0 cm to 10 cm, measured by the investigator. 0 cm referred to absence of itch and 10 cm referred to severe itching. The percent reduction in VAS at Week 18 compared to baseline is reported.
Time Frame	Baseline and Week 18
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.
Participants from the ITT population for whom the VAS assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**30**
Percent Reduction in Visual Analogue Scale (VAS) Referred Itch at Week 18 [units: Percent reduction] Mean (Standard Deviation)	**81 (27)**

No statistical analysis provided for Percent Reduction in Visual Analogue Scale (VAS) Referred Itch at Week 18

18. Secondary: Percent Reduction in VAS Referred Itch at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Percent Reduction in VAS Referred Itch at Week 24
Measure Description	VAS was used to measure itch. Participants reported itch using VAS - a line ranging from 0 cm to 10 cm, measured by the investigator. 0 cm referred to absence of itch and 10 cm referred to severe itching. The percent reduction in VAS at Week 24 compared to baseline is reported.
Time Frame	Baseline and Week 24
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.
Participants from the ITT population for whom the VAS assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**33**
Percent Reduction in VAS Referred Itch at Week 24 [units: Percent reduction] Mean (Standard Deviation)	**72 (38)**

No statistical analysis provided for Percent Reduction in VAS Referred Itch at Week 24

19. Secondary: Percent Reduction in Dermatology Life Quality Index (DLQI) Total Score at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Percent Reduction in Dermatology Life Quality Index (DLQI) Total Score at Week 18
Measure Description	DLQI total score comprises 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. DLQI total scores range from 0 to 30, with 0 corresponding to the best quality of life and 30 to the worst. The percent reduction in DLQI score at Week 18 compared to baseline is reported.
Time Frame	Baseline and Week 18
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.
Participants from the ITT population for whom the DLQI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**30**
Percent Reduction in Dermatology Life Quality Index (DLQI) Total Score at Week 18 [units: Percent reduction] Mean (Standard Deviation)	**77 (35)**

No statistical analysis provided for Percent Reduction in Dermatology Life Quality Index (DLQI) Total Score at Week 18

20. Secondary: Percent Reduction in DLQI Total Score at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Percent Reduction in DLQI Total Score at Week 24
Measure Description	DLQI total score comprises 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. DLQI total scores range from 0 to 30, with 0 corresponding to the best quality of life and 30 to the worst. The percent reduction in DLQI score at Week 24 compared to baseline is reported.
Time Frame	Baseline and Week 24
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.

Participants from the ITT population for whom the DLQI assessment was available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**31**
Percent Reduction in DLQI Total Score at Week 24 [units: Percent reduction] Mean (Standard Deviation)	**68 (50)**

No statistical analysis provided for Percent Reduction in DLQI Total Score at Week 24

21. Secondary: Percent Reduction in Skin Index Questionnaire (SKINDEX-29) Score at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Percent Reduction in Skin Index Questionnaire (SKINDEX-29) Score at Week 18
Measure Description	The SKINDEX-29 measures the quality of life in dermatological participants, who complete a questionnaire assessing 3 scales - burden of symptoms, social functioning and emotional state. Participants answered 29 questions referring to the previous 4-week period, on a 5-point scale from “never” (=0) to “all the time” (=4). The score for each scale ranges from 0 to 100 and higher scores reflect a worse quality of life. The percent reduction in SKINDEX-29 scores at Week 18 compared to baseline is reported.
Time Frame	Baseline and Week 18
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.
Participants from the ITT population for whom the SKINDEX-29 assessments were available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**31**
Percent Reduction in Skin Index Questionnaire (SKINDEX-29) Score at Week 18	

[units: Percent reduction] Mean (Standard Deviation)	
Symptoms score	**42 (26)**
Emotional state score	**39 (25)**
Social functioning score	**39 (27)**

No statistical analysis provided for Percent Reduction in Skin Index Questionnaire (SKINDEX-29) Score at Week 18

22. Secondary: Percent Reduction in SKINDEX-29 Scores at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Percent Reduction in SKINDEX-29 Scores at Week 24
Measure Description	The SKINDEX-29 measures the quality of life in dermatological participants, who complete a questionnaire assessing 3 scales - burden of symptoms, social functioning and emotional state. Participants answered 29 questions referring to the previous 4-week period, on a 5-point scale from “never” (=0) to “all the time” (=4). The score for each scale ranges from 0 to 100 and higher scores reflect a worse quality of life. The percent reduction in SKINDEX-29 scores at Week 24 compared to baseline is reported.
Time Frame	Baseline and Week 24
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.
Participants from the ITT population for whom the SKINDEX-29 assessments were available.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Measured Values

	Infliximab 5 mg/kg
Number of Participants Analyzed [units: participants]	**34**
Percent Reduction in SKINDEX-29 Scores at Week 24 [units: Percent reduction] Mean (Standard Deviation)	
Symptoms score	**40 (29)**
Emotional state score	**32 (34)**
Social functioning score	**31 (36)**

No statistical analysis provided for Percent Reduction in SKINDEX-29 Scores at Week 24

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Serious Adverse Events

	Infliximab 5 mg/kg
Total, serious adverse events	
# participants affected / at risk	**7/38 (18.42%)**
Cardiac disorders	
Mitral Valve Prolapse [1]	
# participants affected / at risk	**1/38 (2.63%)**
# events	**1**
General disorders	
Cyst [1]	
# participants affected / at risk	**1/38 (2.63%)**
# events	**1**
Electrocution [1]	
# participants affected / at risk	**1/38 (2.63%)**
# events	**1**
Injury, poisoning and procedural complications	
Overdose [1]	
# participants affected / at risk	**3/38 (7.89%)**
# events	**4**
Psychiatric disorders	
Completed Suicide [1]	
# participants affected / at risk	**1/38 (2.63%)**
# events	**1**

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg IV administered at Baseline (Week 0), Visit 3 (Week 2), Visit 4 (Week 6), Visit 6 (Week 14), and Visit 8 (Week 22).

Other Adverse Events

	Infliximab 5 mg/kg
Total, other (not including serious) adverse events	
# participants affected / at risk	**12/38 (31.58%)**
Gastrointestinal disorders	
Gastritis [1]	
# participants affected / at risk	**2/38 (5.26%)**
# events	**2**
Infections and infestations	
Bronchitis [1]	
# participants affected / at risk	**2/38 (5.26%)**
# events	**2**
Rhinitis [1]	
# participants affected / at risk	**3/38 (7.89%)**
# events	**3**
Investigations	
Blood Triglycerides Increased [1]	
# participants affected / at risk	**2/38 (5.26%)**
# events	**2**
Transaminases Increased [1]	
# participants affected / at risk	**2/38 (5.26%)**
# events	**2**
Nervous system disorders	
Dizziness [1]	
# participants affected / at risk	**2/38 (5.26%)**
# events	**2**
Skin and subcutaneous tissue disorders	
Pruritus [1]	

# participants affected / at risk	4/38 (10.53%)
# events	11

1 Term from vocabulary, MedDRA 12.1

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:

☑ Investigator agrees not to publish or publicly present any of the study results without prior written authorization from sponsor, except than for the dispositions provided in the Minister’s Decree and Ministerial Circular. Investigator agrees to provide 45 days written notice to sponsor prior to submission for publication or presentation to permit sponsor to review copies of abstracts/manuscripts for publication (including text for oral presentations) which report any study results.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharpe & Dohme Corp
e-mail: ClinicalTrialsDisclosure@merck.com

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00686595 History of Changes
Other Study ID Numbers:	P05133
Study First Received:	May 27, 2008
Results First Received:	January 27, 2011
Last Updated:	February 19, 2016
Health Authority:	Italy: Ministry of Health

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

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