A Study to Evaluate Infliximab in Subjects With Moderate-to-Severe Psoriasis Not Responding to Standard or Biologic Therapy (Study P04612) (ESAQUALITY)

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:
NCT00687401

First received: May 27, 2008
Last updated: October 19, 2015
Last verified: October 2015
History of Changes

Purpose

Subjects with moderate-to-severe chronic psoriasis not responding to standard or biologic therapy will be eligible to enroll in this study. Subjects will receive infliximab infusions (5 mg/kg of body weight) at Weeks 0, 2, 6, and 14 followed by a 12-week follow-up period. The efficacy of infliximab will be evaluated by the Psoriasis Area and Severity Index (PASI).

Condition	Intervention	Phase
Psoriasis	Biological: Infliximab	Phase 3

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

Official Title: A Multi-center, Open Label Trial Evaluating the Efficacy , SAfety and the Impact on QUAlity of Life of Infliximab TherapY in Patients With Moderate-to-severe Psoriasis Not Responding to Standard or Biologic Therapy

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:

- Number of Participants Who Achieve a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI) Score [Time Frame: 10 weeks] [Designated as safety issue: No]

  PASI 75 response is defined as participants who achieved at least a 75% improvement in PASI score from Baseline to Week 10. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their responses to therapy. The PASI produces a numeric score that can range from 0 to 72 (the higher the number, the worse the disease).

Enrollment:	215
Study Start Date:	June 2006
Study Completion Date:	May 2009
Primary Completion Date:	May 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab 5 mg/kg Infliximab 5 mg/kg of body weight administered as an infusion at Weeks 0, 2, 6, and 14.	Biological: Infliximab Infliximab 5 mg/kg of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase). 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, of either gender, and of any race.
- Psoriasis covering at least 10% of total body surface area (BSA) and PASI >=12 at Screening and Baseline.
- Diagnosis of moderate-to-severe psoriasis at least 6 months prior the screening.
- Eligible to infliximab who have failed at least 1 of the following: corticosteroids, methotrexate (MTX), systemic retinoids, cyclosporine, psoralen-ultraviolet A (PUVA), ultraviolet B (UVB) phototherapy, and/or biologics (etanercept or efalizumab).
- Eligible according to tuberculosis (TB) eligibility assessment, screening and early detection of reactivation rules.
- Chest x-ray within 3 months prior to Screening with no evidence of malignancy, infection, or fibrosis.
- Screening and Baseline tests (complete blood count [CBC], blood chemistry, and urinalysis) must be within protocol-specified parameters.
- Free of significant disease that could interfere with study evaluations.
- Willing to give written informed consent and able to adhere to protocol visits and procedures.
- Women of childbearing potential and all men must be using adequate birth control and must continue to do so for 6 months after receiving the last dose of study medication.
- Females of childbearing potential must have a negative serum pregnancy test at Screening and a negative urine pregnancy test at Baseline.

Exclusion Criteria:

- Standard concomitant psoriasis therapies.
- Active or latent TB.
- History of chronic infectious disease, opportunistic infection, or serious infection within 2 months of enrollment.
- History of lymphoproliferative disease.
- Malignancy in past 5 years (except treated basal cell carcinoma [BCC]).
- Treatment with tumor necrosis factor (TNF) antagonists within previous 6 weeks.
- Current drug-induced psoriasis.
- Females who are pregnant or nursing and females and males who are planning pregnancy within 6 months from the last infusion of infliximab.
- Previously treated with infliximab.
- Concomitant diagnosis of congestive heart failure (CHF) including medically-controlled asymptomatic subjects.
- History of chronic or recurrent infectious disease.

- Have or have had a serious infection or have been hospitalized or received intravenous antibiotics for an infection during the 2 months prior to Screening.
- Have or have had an opportunistic infection within 6 months prior to Screening.

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:	NCT00687401 History of Changes
Other Study ID Numbers:	P04612
Study First Received:	May 27, 2008
Results First Received:	December 2, 2010
Last Updated:	October 19, 2015
Health Authority:	Italy: Ministry of Health

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: December 2, 2010

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
No text entered.

Reporting Groups

	Description
Infliximab 5 mg/kg	Infliximab 5 mg/kg of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).

Participant Flow: Overall Study

	Infliximab 5 mg/kg
STARTED	**159** [1]
COMPLETED	**129**
NOT COMPLETED	**30**
Protocol Violation	**7**
Adverse Event	**6**
Lack of Efficacy	**6**
Withdrawal by Subject	**4**
Did not return for visit	**3**
For reasons different from those above	**4**

[1] 215 participants enrolled in the study, of which 56 failed screening and did not receive study drug.

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 of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).

Baseline Measures

	Infliximab 5 mg/kg
Number of Participants [units: participants]	**159**
Age [units: years] Mean (Standard Deviation)	**44.15 (12.80)**
Gender [units: participants]	
Female	**40**
Male	**119**

Outcome Measures

1. Primary: Number of Participants Who Achieve a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI) Score [Time Frame: 10 weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Number of Participants Who Achieve a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI) Score
Measure Description	PASI 75 response is defined as participants who achieved at least a 75% improvement in PASI score from Baseline to Week 10. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their responses to therapy. The PASI produces a numeric score that can range from 0 to 72 (the higher the number, the worse the disease).
Time Frame	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.
Intent to Treat Population (ITT): 159 participants out of the 215 enrolled patients who received at least one dose of the study drug. Per Protocol Population (PP): 138 participants not withdrawn from the study due to major protocol violation and who have received the three infusions of the study drug planned by the protocol.

Reporting Groups

	Description
Intent to Treat Population	Infliximab 5 mg/kg of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).
Per Protocol Population	Infliximab 5 mg/kg of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).

Measured Values

	Intent to Treat Population	**Per Protocol Population**
Number of Participants Analyzed [units: participants]	**159**	**138**
Number of Participants Who Achieve a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI) Score [units: Participants]	**111**	**111**

No statistical analysis provided for Number of Participants Who Achieve a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI) Score

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 of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).

Serious Adverse Events

	Infliximab 5 mg/kg
Total, serious adverse events	
# participants affected / at risk	**2/159 (1.26%)**
Infections and infestations	
pneumonia legionella [1]	
# participants affected / at risk	**1/159 (0.63%)**
# events	**1**
Skin and subcutaneous tissue disorders	
erythema [1]	
# participants affected / at risk	**1/159 (0.63%)**
# 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 of body weight administered as an infusion at Weeks 0, 2, 6 (induction phase), and 14 (maintenance phase).

Other Adverse Events

	Infliximab 5 mg/kg

Total, other (not including serious) adverse events	
# participants affected / at risk	**16/159 (10.06%)**
General disorders	
pyrexia [1]	
# participants affected / at risk	**9/159 (5.66%)**
# events	**10**
Musculoskeletal and connective tissue disorders	
arthralgia [1]	
# participants affected / at risk	**8/159 (5.03%)**
# 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: No specific time period restrictions. If the parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of information, the Sponsor and the Investigator will make good faith efforts to resolve any issues or disagreement.

Results Point of Contact:

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

No publications provided

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