The Effects of Infliximab Versus Methotrexate in the Treatment of Moderate to Severe Psoriasis (Study P04271AM2)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00251641

First received: November 8, 2005
Last updated: January 22, 2015
Last verified: January 2015
History of Changes

Purpose

This is a Phase 3b, randomized, parallel-group, multicenter, active-controlled, open-label study of the efficacy and safety of infliximab compared with methotrexate (MTX) in the treatment of moderate to severe psoriasis in adults who were diagnosed with moderate to severe plaque-type psoriasis for at least 6 months prior to screening (subjects with concurrent psoriatic arthritis may also be enrolled).

Condition	Intervention	Phase
Psoriasis	Drug: infliximab Drug: methotrexate	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open-Label, Randomized Efficacy and Safety Study of Infliximab Versus Methotrexate in the Treatment of Moderate to Severe Psoriasis

Resource links provided by NLM:

MedlinePlus related topics: Psoriasis

Drug Information available for: Methotrexate Methotrexate sodium Infliximab

U.S. FDA Resources

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

Primary Outcome Measures:

- Psoriasis Area and Severity Index 75 (PASI75) Response at Week 16. [Time Frame: 16 weeks] [Designated as safety issue: No]

  PASI75 response is defined as the proportion of participants who achieved at least a 75% improvement in PASI score from Baseline.

Secondary Outcome Measures:

- PASI75 Response at Week 26 [Time Frame: 26 weeks] [Designated as safety issue: No]

  PASI75 response is defined as the proportion of participants who achieved at least a 75% improvement in PASI score from Baseline.

- Proportion of Participants Who Achieved a Physician's Global Assessment (PGA) Score of Cleared or Minimal at Week 16 [Time Frame: 16 weeks] [Designated as safety issue: No]

  PGA is assessed relative to baseline condition and is defined as: clear (100% clear; some residual pinkness or pigmentation: Wornoff's ring may be present), excellent/minimal (75-99% clearing; marked improvement: nearly normal skin texture; some erythema may be present), good (50-74% clearing; moderate improvement: plaque has cleared to point of small scattered papules with normal intervening epidermis), fair (25-49% clearing; slight improvement: decrease in scaling and softening of plaque), poor (0-24% clearing; little or no change in scaling, erythema, or plaque elevation), or worse (worse).

- Proportion of Participants Who Achieved a PGA Score of Cleared or Minimal at Week 26 [Time Frame: 26 weeks] [Designated as safety issue: No]

  PGA is assessed relative to baseline condition and is defined as: clear (100% clear; some residual pinkness or pigmentation: Wornoff's ring may be present), excellent/minimal (75-99% clearing; marked improvement: nearly normal skin texture; some erythema may be present), good (50-74% clearing; moderate improvement: plaque has cleared to point of small scattered papules with normal intervening epidermis), fair (25-49% clearing; slight improvement: decrease in scaling and softening of plaque), poor (0-24% clearing; little or no change in scaling, erythema, or plaque elevation), or worse (worse).

Enrollment:	868
Study Start Date:	September 2005
Study Completion Date:	June 2008
Primary Completion Date:	June 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab	Drug: infliximab The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22. Other Names: • SCH 215596 • Remicade
Active Comparator: Methotrexate	Drug: methotrexate Methotrexate will be supplied as 2.5 mg tablets. Subjects are to take 15 mg/week orally for the first 6 weeks of the study. Subjects will be advised to take their MTX as a single dose (weekly) on the same day of the week. If subjects randomized to MTX 15 mg/week experience a <25% reduction in PASI score at Week 6 (Visit 4) as compared with Baseline, their MTX dose will be increased to 20 mg/week. Subjects will be treated for 22 weeks. Other Names: • Trexall • Rheumatrex

Eligibility

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

Criteria

Inclusion Criteria:

- Adult male and female subjects (>= 18 to 75 years of age) with a diagnosis of moderate to severe plaque-type psoriasis for at least 6 months prior to study screening (subjects with concurrent psoriatic arthritis may also be enrolled).
- Subjects must be eligible for phototherapy or systemic therapy for their psoriasis and must have a Baseline Psoriasis Area and Severity Index (PASI) score of 12 or greater and have at least 10% of their total body surface area (BSA) involved at Baseline.
- Subjects must agree to avoid prolonged sun exposure and avoid use of tanning booths or other ultraviolet light sources during the study.
- Subjects must also meet the tuberculosis (TB) eligibility assessment and screening criteria as follows: Have no history of latent or active TB prior to screening; have no signs or symptoms suggestive of active TB upon medical history and/or physical examination; have had no recent close contact with a person with active TB or, if there has been such contact, will be referred to a physician specializing in TB to undergo additional evaluation and, if warranted, receive appropriate treatment for latent TB prior to or simultaneously with the first administration of study medication; within 1 month prior to the first administration of study medication, either have negative diagnostic TB test results (defined as 2 negative tuberculin skin tests) OR have a newly identified positive diagnostic TB test result (defined as at least 1 positive tuberculin skin tests) during screening in which active TB has been ruled out and for which appropriate treatment for latent TB has been initiated either prior to or simultaneously with the first administration of study medication.
- Subjects must have had a chest x-ray (posterior-anterior and lateral) within 3 months prior to Screening with no evidence of malignancy, infection, fibrosis, or current or old active TB.
- Specific parameters must also be met with regard to screening laboratory test results and liver enzymes in order to be eligible to participate in the study.

Exclusion Criteria:

- Subjects who have non-plaque forms of psoriasis, current drug-induced psoriasis, are pregnant, nursing, or planning pregnancy;
- Subjects previously treated with MTX or infliximab; subjects who are taking specific drugs within the specified time frame prior to Baseline as follows: any therapeutic agent targeted at reducing tumor necrosis factor (TNF) or any biologic, live virus or bacterial vaccinations within 3 months; any systemic medications or treatments that could affect psoriasis or PASI evaluations, or any systemic immunosuppressants or lithium within 4 weeks; any topical medications or treatments that could affect psoriasis or PASI evaluations within 2 weeks. The only allowed topical treatments for psoriasis are shampoos (containing tar or salicylic acid only) and topical moisturizers. Subjects should not use these topical agents during the morning prior to a study visit. Non-medicated shampoos may be used on the morning of a visit.
- Subjects with poor health, including concomitant congestive heart failure (CHF); history of chronic or recurrent infectious disease, as specified; human immunodeficiency virus, hepatitis B, or hepatitis C; demyelinating disease or symptoms suggestive of multiple sclerosis or optic neuritis; systemic lupus erythematosus; or who have had serious infections (eg, hepatitis, pneumonia, or pyelonephritis], or who have been hospitalized or received IV antibiotics, or who had an opportunistic infection (eg, cytomegalovirus, Pneumocystis carinii, aspergillosis, histoplasmosis, or mycobacteria other than TB), or a transplanted organ within specified time frames; or other conditions as specified in the protocol.
- Subjects who have used any investigational drugs within 4 weeks of Screening, who are participating in other clinical studies, staff or family members of study staff are excluded from participation in the study.

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:

Barker J, Hoffmann M, Wozel G, Ortonne JP, Zheng H, van Hoogstraten H, Reich K. Efficacy and safety of infliximab vs. methotrexate in patients with moderate-to-severe plaque psoriasis: results of an open-label, active-controlled, randomized trial (RESTORE1). Br J Dermatol. 2011 Nov;165(5):1109-17. doi: 10.1111/j.1365-2133.2011.10615.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00251641 History of Changes
Other Study ID Numbers:	P04271
Study First Received:	November 8, 2005
Results First Received:	May 21, 2009
Last Updated:	January 22, 2015

Health Authority: Austria: Federal Ministry for Health and Women

Additional relevant MeSH terms:

Psoriasis
Skin Diseases
Skin Diseases, Papulosquamous
Infliximab
Methotrexate
Abortifacient Agents
Abortifacient Agents, Nonsteroidal
Analgesics
Analgesics, Non-Narcotic
Anti-Inflammatory Agents
Anti-Inflammatory Agents, Non-Steroidal
Antimetabolites
Antimetabolites, Antineoplastic
Antineoplastic Agents
Antirheumatic Agents
Central Nervous System Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Gastrointestinal Agents
Immunologic Factors
Immunosuppressive Agents
Molecular Mechanisms of Pharmacological Action
Nucleic Acid Synthesis Inhibitors
Peripheral Nervous System Agents
Pharmacologic Actions
Physiological Effects of Drugs
Reproductive Control Agents
Sensory System Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on July 07, 2015

TO TOP

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

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 21, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Psoriasis
Interventions:	Drug: infliximab Drug: methotrexate

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	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set

	with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
Methotrexate	Methotrexate (MTX) will be supplied as 2.5 mg tablets. Subjects are to take 15 mg/week orally for the first 6 weeks of the study. Subjects will be advised to take their MTX as a single dose (weekly) on the same day of the week. If subjects randomized to MTX 15 mg/week experience a <25% reduction in PASI score at Week 6 (Visit 4) as compared with Baseline, their MTX dose will be increased to 20 mg/week. Subjects will be treated for 22 weeks.

Participant Flow: Overall Study

	Infliximab	Methotrexate
STARTED	**653**	**215**
COMPLETED	**541**	**127**
NOT COMPLETED	**112**	**88**
Adverse Event	**80**	**8**
Lack of Efficacy	**2**	**1**
Progression of Disease	**0**	**2**
Lost to Follow-up	**3**	**3**
Withdrawal by Subject	**6**	**8**
Protocol Violation	**10**	**2**
Did not Meet protocol Eligibility	**2**	**1**
Switched Treatment	**9**	**63**

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	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
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Total	Total of all reporting groups

Baseline Measures

	Infliximab	Methotrexate	Total
Number of Participants [units: participants]	**653**	**215**	**868**
Age [units: years]	**44.1 (18 to 78)**	**41.9 (18 to 69)**	**43.6 (18 to 78)**

Mean (Full Range)			
Gender [units: participants]			
Female	**215**	**67**	**282**
Male	**438**	**148**	**586**

Outcome Measures

Hide All Outcome Measures

1. Primary: Psoriasis Area and Severity Index 75 (PASI75) Response at Week 16. [Time Frame: 16 weeks]

Measure Type	Primary
Measure Title	Psoriasis Area and Severity Index 75 (PASI75) Response at Week 16.
Measure Description	PASI75 response is defined as the proportion of participants who achieved at least a 75% improvement in PASI score from Baseline.
Time Frame	16 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.
All subjects who were randomized were included in the efficacy analysis (intent-to-treat [ITT]).

Reporting Groups

	Description
Infliximab	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
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Measured Values

	Infliximab	**Methotrexate**
Number of Participants Analyzed [units: participants]	**653**	**215**
Psoriasis Area and Severity Index 75 (PASI75) Response at Week 16. [units: Proportion of participants]	**0.78**	**0.42**

Statistical Analysis 1 for Psoriasis Area and Severity Index 75 (PASI75) Response at Week 16.

Groups [1]	All groups
Method [2]	Chi-squared
[3]	

P Value	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The treatment comparison for this endpoint was carried at the 4.9% level of significance.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Pearson's chi-square test
[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.

2. Secondary: PASI75 Response at Week 26 [Time Frame: 26 weeks]

Measure Type	Secondary
Measure Title	PASI75 Response at Week 26
Measure Description	PASI75 response is defined as the proportion of participants who achieved at least a 75% improvement in PASI score from Baseline.
Time Frame	26 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

Reporting Groups

	Description
Infliximab	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
Methotrexate	Methotrexate (MTX) will be supplied as 2.5 mg tablets. Subjects are to take 15 mg/week orally for the first 6 weeks of the study. Subjects will be advised to take their MTX as a single dose (weekly) on the same day of the week. If subjects randomized to MTX 15 mg/week experience a <25% reduction in PASI score at Week 6 (Visit 4) as compared with Baseline, their MTX dose will be increased to 20 mg/week. Subjects will be treated for 22 weeks.

Measured Values

	Infliximab	**Methotrexate**
Number of Participants Analyzed [units: participants]	**653**	**215**
PASI75 Response at Week 26 [units: Proportion of participants]	**0.77**	**0.31**

Statistical Analysis 1 for PASI75 Response at Week 26

Groups [1]	All groups

Method [2]	Chi-squared
P Value [3]	<0.001

[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:
	Pearson's chi-square test
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Multiplicity adjustment was provided using Hochberg test.

3. Secondary: Proportion of Participants Who Achieved a Physician's Global Assessment (PGA) Score of Cleared or Minimal at Week 16 [Time Frame: 16 weeks]

Measure Type	Secondary
Measure Title	Proportion of Participants Who Achieved a Physician's Global Assessment (PGA) Score of Cleared or Minimal at Week 16
Measure Description	PGA is assessed relative to baseline condition and is defined as: clear (100% clear; some residual pinkness or pigmentation: Wornoff's ring may be present), excellent/minimal (75-99% clearing; marked improvement: nearly normal skin texture; some erythema may be present), good (50-74% clearing; moderate improvement: plaque has cleared to point of small scattered papules with normal intervening epidermis), fair (25-49% clearing; slight improvement: decrease in scaling and softening of plaque), poor (0-24% clearing; little or no change in scaling, erythema, or plaque elevation), or worse (worse).
Time Frame	16 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.
ITT

Reporting Groups

	Description
Infliximab	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
Methotrexate	Methotrexate (MTX) will be supplied as 2.5 mg tablets. Subjects are to take 15 mg/week orally for the first 6 weeks of the study. Subjects will be advised to take their MTX as a single dose (weekly) on the same day of the week. If subjects randomized to MTX 15 mg/week experience a <25% reduction in PASI score at Week 6 (Visit 4) as compared with Baseline, their MTX dose will be increased to 20 mg/week. Subjects will be treated for 22 weeks.

Measured Values

	Infliximab	**Methotrexate**
Number of Participants Analyzed	**653**	**215**

[units: participants]		
Proportion of Participants Who Achieved a Physician's Global Assessment (PGA) Score of Cleared or Minimal at Week 16 [units: Proportion of participants]	**0.76**	**0.38**

Statistical Analysis 1 for Proportion of Participants Who Achieved a Physician's Global Assessment (PGA) Score of Cleared or Minimal at Week 16

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	<0.001

[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:
	Pearson's chi-square test
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Multiplicity adjustment was provided using the Hochberg test.

4. Secondary: Proportion of Participants Who Achieved a PGA Score of Cleared or Minimal at Week 26 [Time Frame: 26 weeks]

Measure Type	Secondary
Measure Title	Proportion of Participants Who Achieved a PGA Score of Cleared or Minimal at Week 26
Measure Description	PGA is assessed relative to baseline condition and is defined as: clear (100% clear; some residual pinkness or pigmentation: Wornoff's ring may be present), excellent/minimal (75-99% clearing; marked improvement: nearly normal skin texture; some erythema may be present), good (50-74% clearing; moderate improvement: plaque has cleared to point of small scattered papules with normal intervening epidermis), fair (25-49% clearing; slight improvement: decrease in scaling and softening of plaque), poor (0-24% clearing; little or no change in scaling, erythema, or plaque elevation), or worse (worse).
Time Frame	26 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.
ITT

Reporting Groups

	Description
Infliximab	The infliximab dose will be prepared according to the subject's weight (5 mg/kg). Each intravenous (IV) infusion will be administered over a period of not less than 2 hours. The infusion must be given via a separate line using the administration set with a 1.2 micron filter. Subjects will be infused at Weeks 0, 2, 6, 14, and 22.
Methotrexate	Methotrexate (MTX) will be supplied as 2.5 mg tablets. Subjects are to take 15 mg/week orally for the first 6 weeks of the study. Subjects will be advised to take their MTX as a single dose (weekly) on the same day of the week. If subjects randomized to MTX 15 mg/week experience a <25% reduction in PASI score at Week 6 (Visit 4) as compared with Baseline, their MTX dose

	will be increased to 20 mg/week. Subjects will be treated for 22 weeks.

Measured Values

	Infliximab	Methotrexate
Number of Participants Analyzed [units: participants]	**653**	**215**
Proportion of Participants Who Achieved a PGA Score of Cleared or Minimal at Week 26 [units: Proportion of participants]	**0.73**	**0.28**

Statistical Analysis 1 for Proportion of Participants Who Achieved a PGA Score of Cleared or Minimal at Week 26

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	<0.001

[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:
	Pearson's chi-square test
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Multiplicity adjustment was provided using the Hochberg test.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Infliximab	Adverse events reported through Week 26 for participants who did not switch treatment at Week 16 and adverse reported through Week 16 for those participants who switched treatment.
Methotrexate	Adverse events reported through Week 26 for participants who did not switch treatment at Week 16 and adverse reported through Week 16 for those participants who switched treatment.
Participants Who Switched From Infliximab to Methotrexate	Adverse events reported for participants who switched from infliximab to methotrexate at Week 16 (including only adverse events with begin dates on or after a switch in treatment).
Participants Who Switched From Methotrexate to Infliximab	Adverse events reported for participants who switched from methotrexate to infliximab at Week 16 (including only adverse events with begin dates on or after a switch in treatment).

Serious Adverse Events

	Infliximab	Methotrexate	Participants Who Switched From Infliximab to Methotrexate	Participants Who Switched From Methotrexate to Infliximab
Total, serious adverse events				
# participants affected / at risk	**44/649 (6.78%)**	**6/211 (2.84%)**	**0/9 (0.00%)**	**3/63 (4.76%)**
Blood and lymphatic system disorders				
THROMBOCYTOPENIA † 1				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
Cardiac disorders				
ANGINA PECTORIS † 1				
# participants affected / at risk	**1/649 (0.15%)**	**1/211 (0.47%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**1**	**0**	**0**
ATRIAL FIBRILLATION † 1				
# participants affected / at risk	**2/649 (0.31%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**2**	**0**	**0**	**0**
MYOCARDIAL INFARCTION † 1				
# participants affected / at risk	**0/649 (0.00%)**	**1/211 (0.47%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**1**	**0**	**0**
PERICARDITIS † 1				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
Congenital, familial and genetic disorders				
PHIMOSIS † 1				
# participants affected / at risk	**0/649 (0.00%)**	**1/211 (0.47%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**1**	**0**	**0**
Eye disorders				
IRIDOCYCLITIS † 1				
# participants affected / at risk	**0/649 (0.00%)**	**1/211 (0.47%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**1**	**0**	**0**
MACULAR HOLE † 1				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
Gastrointestinal disorders				
GASTRITIS † 1				

# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
General disorders				
INFUSION RELATED REACTION † 1				
# participants affected / at risk	8/649 (1.23%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	10	0	0	0
OEDEMA PERIPHERAL † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PYREXIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Hepatobiliary disorders				
AUTOIMMUNE HEPATITIS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
BILIARY COLIC † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
CHOLECYSTITIS † 1				
# participants affected / at risk	2/649 (0.31%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	2	0	0	0
CHOLECYSTITIS ACUTE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
CHOLELITHIASIS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Immune system disorders				
HYPERSENSITIVITY † 1				
# participants affected / at risk	2/649 (0.31%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	3	0	0	0
TYPE IV HYPERSENSITIVITY REACTION † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Infections and infestations				
† 1				

ARTHRITIS BACTERIAL				
# participants affected / at risk	**0/649 (0.00%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**1/63 (1.59%)**
# events	**0**	**0**	**0**	**1**
FEBRILE INFECTION † [1]				
# participants affected / at risk	**0/649 (0.00%)**	**1/211 (0.47%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**1**	**0**	**0**
LYME DISEASE † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
PHARYNGITIS STREPTOCOCCAL † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
PNEUMONIA † [1]				
# participants affected / at risk	**2/649 (0.31%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**2**	**0**	**0**	**0**
PULMONARY TUBERCULOSIS † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
STAPHYLOCOCCAL INFECTION † [1]				
# participants affected / at risk	**0/649 (0.00%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**1/63 (1.59%)**
# events	**0**	**0**	**0**	**1**
VIRAL INFECTION † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
Injury, poisoning and procedural complications				
CERVICAL VERTEBRAL FRACTURE † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
FACIAL BONES FRACTURE † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
MENISCUS LESION † [1]				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**
Investigations				
HEPATIC ENZYME INCREASED † [1]				

# participants affected / at risk	2/649 (0.31%)	1/211 (0.47%)	0/9 (0.00%)	0/63 (0.00%)
# events	2	1	0	0
Metabolism and nutrition disorders				
DIABETES MELLITUS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Musculoskeletal and connective tissue disorders				
ARTHRALGIA † 1				
# participants affected / at risk	3/649 (0.46%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	3	0	0	0
ARTHRITIS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
LUPUS-LIKE SYNDROME † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
MYALGIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PAIN IN EXTREMITY † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PSORIATIC ARTHROPATHY † 1				
# participants affected / at risk	0/649 (0.00%)	0/211 (0.00%)	0/9 (0.00%)	1/63 (1.59%)
# events	0	0	0	1
SPINAL COLUMN STENOSIS † 1				
# participants affected / at risk	0/649 (0.00%)	1/211 (0.47%)	0/9 (0.00%)	0/63 (0.00%)
# events	0	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
FOCAL NODULAR HYPERPLASIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
TESTICULAR NEOPLASM † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Nervous system disorders				

DYSAESTHESIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
HYPOAESTHESIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
NEUROPATHY PERIPHERAL † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PARAESTHESIA † 1				
# participants affected / at risk	0/649 (0.00%)	1/211 (0.47%)	0/9 (0.00%)	0/63 (0.00%)
# events	0	1	0	0
SYNCOPE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Renal and urinary disorders				
NEPHROLITHIASIS † 1				
# participants affected / at risk	0/649 (0.00%)	1/211 (0.47%)	0/9 (0.00%)	0/63 (0.00%)
# events	0	1	0	0
NOCTURIA † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Reproductive system and breast disorders				
OVARIAN HAEMORRHAGE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Respiratory, thoracic and mediastinal disorders				
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
DYSPNOEA † 1				
# participants affected / at risk	1/649 (0.15%)	1/211 (0.47%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	1	0	0
INTERSTITIAL LUNG DISEASE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)

# events	1	0	0	0
PLEURISY † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PRODUCTIVE COUGH † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PULMONARY EMBOLISM † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
RESPIRATORY FAILURE † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
Skin and subcutaneous tissue disorders				
NIGHT SWEATS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0
PSORIASIS † 1				
# participants affected / at risk	2/649 (0.31%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	2	0	0	0
Vascular disorders				
HYPERTENSION † 1				
# participants affected / at risk	0/649 (0.00%)	0/211 (0.00%)	0/9 (0.00%)	1/63 (1.59%)
# events	0	0	0	1
THROMBOSIS † 1				
# participants affected / at risk	1/649 (0.15%)	0/211 (0.00%)	0/9 (0.00%)	0/63 (0.00%)
# events	1	0	0	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

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	Adverse events reported through Week 26 for participants who did not switch treatment at Week 16 and adverse reported through Week 16 for those participants who switched treatment.
Methotrexate	Adverse events reported through Week 26 for participants who did not switch treatment at Week 16 and adverse reported through Week 16 for those participants who switched treatment.
Participants Who Switched From Infliximab to Methotrexate	Adverse events reported for participants who switched from infliximab to methotrexate at Week 16 (including only adverse events with begin dates on or after a switch in treatment).
Participants Who Switched From Methotrexate to Infliximab	Adverse events reported for participants who switched from methotrexate to infliximab at Week 16 (including only adverse events with begin dates on or after a switch in treatment).

Other Adverse Events

	Infliximab	Methotrexate	Participants Who Switched From Infliximab to Methotrexate	Participants Who Switched From Methotrexate to Infliximab
Total, other (not including serious) adverse events				
# participants affected / at risk	**275/649 (42.37%)**	**95/211 (45.02%)**	**1/9 (11.11%)**	**11/63 (17.46%)**
Gastrointestinal disorders				
ABDOMINAL PAIN UPPER † 1				
# participants affected / at risk	**7/649 (1.08%)**	**11/211 (5.21%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**9**	**27**	**0**	**0**
DIARRHOEA † 1				
# participants affected / at risk	**21/649 (3.24%)**	**17/211 (8.06%)**	**0/9 (0.00%)**	**1/63 (1.59%)**
# events	**22**	**34**	**0**	**1**
NAUSEA † 1				
# participants affected / at risk	**21/649 (3.24%)**	**20/211 (9.48%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**30**	**77**	**0**	**0**
General disorders				
FATIGUE † 1				
# participants affected / at risk	**26/649 (4.01%)**	**19/211 (9.00%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**28**	**39**	**0**	**0**
INFUSION RELATED REACTION † 1				
# participants affected / at risk	**70/649 (10.79%)**	**0/211 (0.00%)**	**0/9 (0.00%)**	**5/63 (7.94%)**
# events	**139**	**0**	**0**	**10**
Infections and infestations				

NASOPHARYNGITIS † 1				
# participants affected / at risk	**119/649 (18.34%)**	**40/211 (18.96%)**	**0/9 (0.00%)**	**3/63 (4.76%)**
# events	**157**	**46**	**0**	**3**
Musculoskeletal and connective tissue disorders				
ARTHRALGIA † 1				
# participants affected / at risk	**41/649 (6.32%)**	**12/211 (5.69%)**	**0/9 (0.00%)**	**0/63 (0.00%)**
# events	**54**	**15**	**0**	**0**
Nervous system disorders				
HEADACHE † 1				
# participants affected / at risk	**66/649 (10.17%)**	**31/211 (14.69%)**	**0/9 (0.00%)**	**5/63 (7.94%)**
# events	**111**	**74**	**0**	**7**
Reproductive system and breast disorders				
EPIDIDYMITIS † 1				
# participants affected / at risk	**1/649 (0.15%)**	**0/211 (0.00%)**	**1/9 (11.11%)**	**0/63 (0.00%)**
# events	**1**	**0**	**1**	**0**
Skin and subcutaneous tissue disorders				
PRURITUS † 1				
# participants affected / at risk	**39/649 (6.01%)**	**4/211 (1.90%)**	**0/9 (0.00%)**	**1/63 (1.59%)**
# events	**50**	**4**	**0**	**2**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

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:** PI must provide sponsor w/ review copies of abstracts or manuscripts for publication that report any results of the study, 45 days before submission for publication or presentation. The sponsor shall have the right to review/comment on the material. If the parties disagree about the appropriateness of the material, PI must meet with sponsor's representatives before submission for publication, for the purpose of making good faith efforts to discuss and resolve any issues of disagreement.

Results Point of Contact:

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

Publications of Results:

Barker J, Hoffmann M, Wozel G, Ortonne JP, Zheng H, van Hoogstraten H, Reich K. Efficacy and safety of infliximab vs. methotrexate in patients with moderate-to-severe plaque psoriasis: results of an open-label, active-controlled, randomized trial (RESTORE1). Br J Dermatol. 2011 Nov;165(5):1109-17. doi: 10.1111/j.1365-2133.2011.10615.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00251641 History of Changes
Other Study ID Numbers:	P04271
Study First Received:	November 8, 2005
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Last Updated:	January 22, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

TO TOP

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

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