Long-Term Effects of Infliximab in the Treatment of Moderate to Severe Psoriasis [Extension of Study P04271, NCT00251641] (P04563)

This study has been terminated.

(Infusion reactions during re-induction cycles after a period of no treatment. Please see "Purpose" section.)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00358670

First received: July 31, 2006
Last updated: January 22, 2015
Last verified: January 2015
History of Changes

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

Purpose

This is a long-term, randomized, multi-center, open-label study of infliximab treatment in adults with moderate to severe plaque-type psoriasis. This study is the long-term extension of Study P04271 (NCT00251641); Study P04271 is a Phase 3b, randomized, parallel-group, multicenter, open-label, 26-week study comparing the efficacy and safety of infliximab versus methotrexate in the treatment of adult subjects with moderate to severe plaque-type psoriasis. The objectives of this study are to assess the efficacy and safety of long-term maintenance therapy versus intermittent therapy with 5 mg/kg infliximab in a moderate to severe plaque-type psoriasis population.

During an interim safety evaluation of the trial, a higher incidence of serious and severe infusion reactions was observed in the intermittent treatment arm, consisting of a re-induction cycle (maximum of 4 infusions at 0, 2, 6 and 14 weeks) after a period of no treatment compared with the maintenance arm (infusions every 8 weeks without an interruption of treatment). Consequently, the sponsor has terminated the trial. The label will be updated to reflect this new information relating to the use of a re-induction regimen with infliximab.

Condition	Intervention	Phase
Psoriasis	Biological: infliximab	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: A Long-Term Efficacy and Safety Study of Infliximab in the Treatment of Moderate to Severe Plaque-Type Psoriasis

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 Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128 [Time Frame: 128 weeks] [Designated as safety issue: No]

  PASI75 defined as the number of participants who achieved a >=75% improvement in Psoriasis Area and Severity Index (PASI) from the original Baseline in Study P04271 (NCT00251641).

Secondary Outcome Measures:

- Number of Participants Who Achieved PASI75 Response at Week 52 [Time Frame: 52 weeks] [Designated as safety issue: No]

  PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in Study P04271 (NCT00251641)

- Number of Participants Who Achieved PASI75 Response at Week 100 [Time Frame: 100 Weeks] [Designated as safety issue: No]

  PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in Study P04271 (NCT00251641)

- PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period) [Time Frame: Day 0 to 180 days] [Designated as safety issue: No]

  The PASI 6-month AUC is a time adjusted total PASI score over the 6 month (180 days) period. The AUC is a continuous measurement (not a score on a scale); a lower value is considered better and a higher value is considered worse. The weighted average PASI score over 6 months (using all available PASI scores during a 6 month period [from Day 0 to 180 days]) is obtained by using PASI 6-month AUC /180 days.

- PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period) [Time Frame: Day 0 to 360 days] [Designated as safety issue: No]

  The PASI 12-month AUC is a time adjusted total PASI score over the 12 month (360 days) period. The AUC is a continuous measurement (not a score on a scale); and a lower value is considered better. The weighted average PASI score over 12 months (using all available PASI scores during a 12 month period [from Day 0 to 360 days]) is is obtained by using PASI 12-month AUC /360 days.

Enrollment:	441
Study Start Date:	May 2006
Study Completion Date:	January 2009
Primary Completion Date:	January 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Maintenance Infliximab Infliximab 5 mg/kg by body weight every 8 weeks	Biological: infliximab Infliximab maintenance therapy intravenous (IV) infusion every 8 weeks, 5 mg/kg body weight (first infusion at Week 4/Visit 2). Other Names: • SCH 215596 • Remicade
Experimental: Intermittent Infliximab Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50%	Biological: infliximab Infliximab intermittent therapy: Paricipants will receive no infliximab treatment until the Week 26 improvement in PASI from Baseline (original Study P04271 [NCT00251641] Baseline) is reduced by more than 50%. At that time, participants will receive an infliximab infusion, 5 mg/kg body weight. Participants may receive additional infusions at 0, 2, 6, and 14 weeks after the first infusion of the cycle (ie, a maximum of 4 infusions in each infusion cycle) as needed until they respond, defined as a >=75% improvement in PASI from the original Baseline in Study P04271. Subjects will receive no further treatment until

reduction in Psoriasis Area and Severity Index (PASI) from the Study P04271 Baseline	they relapse again (ie, improvement in PASI from Baseline is reduced by more than 50%), at which time participants will receive another infusion cycle of up to 4 infusions, as described above. Throughout the study, intermittent treatment infusion cycles will be repeated whenever participants relapse. Other Names: • SCH 215596 • Remicade

Eligibility

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

Criteria

Inclusion Criteria:

- Subjects must have met all inclusion/exclusion criteria in Study P04271 (NCT00251641).
- Subjects must have been originally randomized to infliximab in Study P04271.
- Subjects must have completed the full 26 weeks of Study P04271.
- Subjects must have remained on infliximab for the full 22 weeks of treatment in Study P04271.
- Subjects must have achieved an improvement in Psoriasis Area and Severity Index (PASI) score >=75% from Baseline of Study P04271 to Week 26 of Study P04271.
- Subjects must agree to avoid prolonged sun exposure and avoid use of tanning booths or other ultraviolet light sources during the study.
- Subjects are considered eligible according to the following tuberculosis (TB) criteria:
  - 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.
- Subjects' Baseline (Visit 1) clinical laboratory tests (complete blood count, blood chemistry, and urinalysis) must be within the following parameters:
  - Hemoglobin >=10 g/dL
  - White blood cells >=3.5 x 10^9/L
  - Neutrophils >=1.5 x 10^9/L
  - Platelets >=100 x 10^9/L
  - Serum creatinine <1.5 mg/dL (or <133 umol/L)
  - Aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma-glutamyltransferase levels as outlined in Protocol P04563.
  - Total bilirubin <2 x upper limit of normal [Note: If Baseline laboratory tests are not yet available, then the previous laboratory tests from Week 22 of the parent study (Study P04271) should be used for enrollment. When the Baseline laboratory tests become available, the investigator must apply the above parameters to determine a subject's eligibility.]
- Subjects must be free of any clinically significant disease (other than plaque-type psoriasis or psoriatic arthritis) that would interfere with the study evaluations.
- Subjects must be willing to give written informed consent and be able to adhere to dose and visit schedules.
- Women of childbearing potential and all men must be using adequate birth control measures (eg, abstinence, oral contraceptives, intrauterine device, barrier method with spermicide, or surgical sterilization) and must continue using such measures until 6 months after receiving the last infusion of study medication.
- Female subjects of childbearing potential must have a negative urine pregnancy test at Baseline.

Exclusion Criteria:

- Subjects who have any significant ongoing adverse events (AEs) or AEs from Study P04271 (NCT00251641) that would prohibit further treatment with infliximab at the time of entry.
- Subjects originally randomized to methotrexate or subjects who received methotrexate at any time during their participation in Study P04271.
- Subjects who have non-plaque forms of psoriasis (eg, erythrodermic, guttate, or pustular).
- Subjects who have current drug-induced psoriasis (eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium

channel blockers, or lithium).

- Female subjects who are pregnant, nursing, and both men and women who are planning pregnancy during the study period or during the 6 months after receiving of the last infusion of study medication.
- Subjects who are in a situation or have any condition that, in the opinion of the investigator, may interfere with optimal participation in the study.
- Subjects who are staff personnel directly involved with this study.
- Subjects who are family members of the 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

Publications:

Reich K, Wozel G, Zheng H, van Hoogstraten HJ, Flint L, Barker J. Efficacy and safety of infliximab as continuous or intermittent therapy in patients with moderate-to-severe plaque psoriasis: results of a randomized, long-term extension trial (RESTORE2). Br J Dermatol. 2013 Jun;168(6):1325-34. doi: 10.1111/bjd.12404.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00358670 History of Changes
Other Study ID Numbers:	P04563 EUDRACT NUMBER:2005-005367-28
Study First Received:	July 31, 2006
Results First Received:	April 8, 2010
Last Updated:	January 22, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

Additional relevant MeSH terms:

Psoriasis	Central Nervous System Agents
Skin Diseases	Dermatologic Agents
Skin Diseases, Papulosquamous	Gastrointestinal Agents
Antibodies, Monoclonal	Immunologic Factors
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 11, 2016

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

Long-Term Effects of Infliximab in the Treatment of Moderate to Severe Psoriasis [Extension of Study P04271, NCT00251641] (P04563)

This study has been terminated.

(Infusion reactions during re-induction cycles after a period of no treatment. Please see "Purpose" section.)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00358670

First received: July 31, 2006
Last updated: January 22, 2015
Last verified: January 2015
History of Changes

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

Results First Received: April 8, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel 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
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in Psoriasis Area and Severity Index (PASI) from the Study P04271 (NCT00251641) Baseline

Participant Flow: Overall Study

	Maintenance Infliximab	Intermittent Infliximab
STARTED	**222**	**219**
COMPLETED	**0**	**0**
NOT COMPLETED	**222**	**219**
Adverse Event	**26**	**29**
Lack of Efficacy	**20**	**23**
Protocol Violation	**6**	**9**
Lost to Follow-up	**4**	**5**
Withdrawal by Subject	**13**	**24**
Protocol Defined Clinical Event	**0**	**1**
Did Not Meet Protocol Eligibility	**0**	**3**
Administrative	**153**	**125**

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
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline
Total	Total of all reporting groups

Baseline Measures

	Maintenance Infliximab	Intermittent Infliximab	Total
Number of Participants [units: participants]	**222**	**219**	**441**
Age [units: years] Mean (Standard Deviation)	**45.7 (12.1)**	**43.3 (12.2)**	**44.5 (12.2)**

Gender [units: participants]			
Female	**70**	**63**	**133**
Male	**152**	**156**	**308**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128 [Time Frame: 128 weeks]

Measure Type	Primary
Measure Title	Number of Participants Who Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128
Measure Description	PASI75 defined as the number of participants who achieved a >=75% improvement in Psoriasis Area and Severity Index (PASI) from the original Baseline in Study P04271 (NCT00251641).
Time Frame	128 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.
Due to the early termination of the study, no subjects completed 128 weeks of therapy.

Reporting Groups

	Description
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline

Measured Values

	Maintenance Infliximab	**Intermittent Infliximab**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants Who Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128		

No statistical analysis provided for Number of Participants Who Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128

2. Secondary: Number of Participants Who Achieved PASI75 Response at Week 52 [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved PASI75 Response at Week 52
Measure Description	PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in

	Study P04271 (NCT00251641)
Time Frame	52 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.
Descriptive summary of all randomized subjects who completed 52 weeks (+ or - 4 weeks) of therapy. Based on best (minimum) PASI score at Week 52.

Reporting Groups

	Description
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline

Measured Values

	Maintenance Infliximab	**Intermittent Infliximab**
Number of Participants Analyzed [units: participants]	**101**	**83**
Number of Participants Who Achieved PASI75 Response at Week 52 [units: Participants]	**81**	**39**

No statistical analysis provided for Number of Participants Who Achieved PASI75 Response at Week 52

3. Secondary: Number of Participants Who Achieved PASI75 Response at Week 100 [Time Frame: 100 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved PASI75 Response at Week 100
Measure Description	PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in Study P04271 (NCT00251641)
Time Frame	100 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.
Descriptive summary of all randomized subjects who completed 100 weeks (+ or - 4 weeks) of therapy. Based on best (minimum) PASI score at Week 100.

Reporting Groups

	Description
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks

Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline

Measured Values

	Maintenance Infliximab	Intermittent Infliximab
Number of Participants Analyzed [units: participants]	**21**	**13**
Number of Participants Who Achieved PASI75 Response at Week 100 [units: Participants]	**18**	**9**

No statistical analysis provided for Number of Participants Who Achieved PASI75 Response at Week 100

4. Secondary: PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period) [Time Frame: Day 0 to 180 days]

Measure Type	Secondary
Measure Title	PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period)
Measure Description	The PASI 6-month AUC is a time adjusted total PASI score over the 6 month (180 days) period. The AUC is a continuous measurement (not a score on a scale); a lower value is considered better and a higher value is considered worse. The weighted average PASI score over 6 months (using all available PASI scores during a 6 month period [from Day 0 to 180 days]) is obtained by using PASI 6-month AUC /180 days.
Time Frame	Day 0 to 180 days
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 with at least two post Study P04563 randomization PASI scores (at least one is 150 days or more from Study P04563 randomization).

Reporting Groups

	Description
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline

Measured Values

	Maintenance Infliximab	Intermittent Infliximab
Number of Participants Analyzed [units: participants]	**186**	**183**
PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period) [units: 6-month PASI AUC] Mean (Standard Error)	**566.2 (51.22)**	**1098.0 (53.48)**

No statistical analysis provided for PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period)

5. Secondary: PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period) [Time Frame: Day 0 to 360 days]

Measure Type	Secondary
Measure Title	PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period)
Measure Description	The PASI 12-month AUC is a time adjusted total PASI score over the 12 month (360 days) period. The AUC is a continuous measurement (not a score on a scale); and a lower value is considered better. The weighted average PASI score over 12 months (using all available PASI scores during a 12 month period [from Day 0 to 360 days]) is is obtained by using PASI 12-month AUC /360 days.
Time Frame	Day 0 to 360 days
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 with at least two post Study P04563 randomization PASI scores (at least one is 330 days or more from Study P04563 randomization).

Reporting Groups

	Description
Maintenance Infliximab	Infliximab 5 mg/kg by body weight every 8 weeks
Intermittent Infliximab	Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in PASI from the Study P04271 (NCT00251641) Baseline

Measured Values

	Maintenance Infliximab	**Intermittent Infliximab**
Number of Participants Analyzed [units: participants]	**105**	**91**
PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period) [units: 12-month PASI AUC] Mean (Standard Error)	**860.7 (92.46)**	**2214.2 (108.5)**

No statistical analysis provided for PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Maintenance Infliximab	No text entered.
Intermittent Infliximab	No text entered.

Serious Adverse Events

	Maintenance Infliximab	Intermittent Infliximab
Total, serious adverse events		
# participants affected / at risk	**24/222 (10.81%)**	**23/219 (10.50%)**
Blood and lymphatic system disorders		
LYMPHADENOPATHY † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
Cardiac disorders		
ATRIAL FIBRILLATION † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
MYOCARDIAL INFARCTION † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
Eye disorders		
MACULAR HOLE † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
DIARRHOEA † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
HAEMORRHOIDS † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
INGUINAL HERNIA † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
General disorders		
CHEST DISCOMFORT † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**

# events	1	0
CHEST PAIN † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
HYPOTHERMIA † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
INFUSION RELATED REACTION † 1		
# participants affected / at risk	1/222 (0.45%)	8/219 (3.65%)
# events	1	10
POLYSEROSITIS † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
Immune system disorders		
DRUG HYPERSENSITIVITY † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
Infections and infestations		
ABSCESS JAW † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
ACUTE TONSILLITIS † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
DISSEMINATED TUBERCULOSIS † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
DIVERTICULITIS † 1		
# participants affected / at risk	2/222 (0.90%)	0/219 (0.00%)
# events	2	0
GASTROENTERITIS † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
GASTROINTESTINAL INFECTION † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
INFECTION † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
INFLUENZA † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
PNEUMONIA † 1		
# participants affected / at risk	2/222 (0.90%)	0/219 (0.00%)
# events	2	0

PULMONARY TUBERCULOSIS † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
SUBCUTANEOUS ABSCESS † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
TONSILLITIS † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
ALCOHOL POISONING † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**2**	**0**
HUMERUS FRACTURE † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
MENISCUS LESION † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**2**	**0**
Investigations		
BIOPSY PROSTATE † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
HEPATIC ENZYME INCREASED † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
Metabolism and nutrition disorders		
DEHYDRATION † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**
# events	**0**	**1**
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	**2/222 (0.90%)**	**1/219 (0.46%)**
# events	**2**	**1**
INTERVERTEBRAL DISC PROTRUSION † 1		
# participants affected / at risk	**0/222 (0.00%)**	**2/219 (0.91%)**
# events	**0**	**2**
MUSCULAR WEAKNESS † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
MYALGIA † 1		
# participants affected / at risk	**1/222 (0.45%)**	**0/219 (0.00%)**
# events	**1**	**0**
PSORIATIC ARTHROPATHY † 1		
# participants affected / at risk	**0/222 (0.00%)**	**1/219 (0.46%)**

# events	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
BASAL CELL CARCINOMA † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
COLON CANCER † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
LUNG NEOPLASM MALIGNANT † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
Nervous system disorders		
SCIATICA † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
SYNCOPE † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
Psychiatric disorders		
ALCOHOL ABUSE † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
MAJOR DEPRESSION † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
Renal and urinary disorders		
ACUTE PRERENAL FAILURE † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
Reproductive system and breast disorders		
BENIGN PROSTATIC HYPERPLASIA † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
PNEUMOTHORAX † 1		
# participants affected / at risk	0/222 (0.00%)	1/219 (0.46%)
# events	0	1
Skin and subcutaneous tissue disorders		
ANGIOEDEMA † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0
PSORIASIS † 1		
# participants affected / at risk	1/222 (0.45%)	1/219 (0.46%)

# events	1	1
PUSTULAR PSORIASIS † 1		
# participants affected / at risk	1/222 (0.45%)	0/219 (0.00%)
# events	1	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0

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
Maintenance Infliximab	No text entered.
Intermittent Infliximab	No text entered.

Other Adverse Events

	Maintenance Infliximab	Intermittent Infliximab
Total, other (not including serious) adverse events		
# participants affected / at risk	95/222 (42.79%)	97/219 (44.29%)
General disorders		
INFUSION RELATED REACTION † 1		
# participants affected / at risk	20/222 (9.01%)	25/219 (11.42%)
# events	43	49
Infections and infestations		
NASOPHARYNGITIS † 1		
# participants affected / at risk	46/222 (20.72%)	48/219 (21.92%)
# events	67	64
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	22/222 (9.91%)	30/219 (13.70%)
# events	33	40
BACK PAIN † 1		

# participants affected / at risk	**10/222 (4.50%)**	**11/219 (5.02%)**
# events	**15**	**14**
Nervous system disorders		
HEADACHE † 1		
# participants affected / at risk	**14/222 (6.31%)**	**23/219 (10.50%)**
# events	**24**	**41**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0

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:** The only disclosure restriction on the PI is that the sponsor can review results communications prior to release and can embargo communications regarding trial results for a period that is less than or equal to 45 days from the time submitted to the sponsor for review. If the parties disagree on the communication, the investigator and sponsor's representative will meet for the purpose of making a good faith effort to discuss and resolve any such issues or disagreement.

Results Point of Contact:

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

Publications of Results:

Reich K, Wozel G, Zheng H, van Hoogstraten HJ, Flint L, Barker J. Efficacy and safety of infliximab as continuous or intermittent therapy in patients with moderate-to-severe plaque psoriasis: results of a randomized, long-term extension trial (RESTORE2). Br J Dermatol. 2013 Jun;168(6):1325-34. doi: 10.1111/bjd.12404.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00358670 History of Changes
Other Study ID Numbers:	P04563 EUDRACT NUMBER:2005-005367-28
Study First Received:	July 31, 2006
Results First Received:	April 8, 2010
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

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