Dose Optimization of Infliximab in Moderate to Severe Plaque Psoriasis (Study P05315) (DOSE)

This study has been terminated.

(In Amendment 1 of P05319 [NCT 00779675], the option to enroll into this study, was discontinued due to low numbers of participants with suboptimal response.)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00833053

First received: January 29, 2009
Last updated: August 13, 2015
Last verified: August 2015
History of Changes

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

Purpose

Participants from an ongoing observational study (P05319) who have a limited (adequate but less than optimal) response to infliximab will be randomized to either increase the frequency of infliximab infusions from every 8 weeks to every 6 weeks, or to add weekly methotrexate to their current treatment plan. While receiving infliximab study treatment(s), patients in this study will attend regularly scheduled office visits for various clinical tests for safety and effectiveness evaluations.

Condition	Intervention	Phase
Psoriasis	Drug: Infliximab Drug: Infliximab and methotrexate	Phase 3

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

Official Title: A Study of Dose Optimization of Infliximab in the Treatment of Moderate to Severe Plaque 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:

- Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The Psoriasis Area and Sensitivity Index (PASI) is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-75 response indicates the number of participants achieving a 75% reduction in PASI score compared to baseline.

Secondary Outcome Measures:

- Number of Participants With A PASI-50 Response at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.The PASI-50 response indicates the number of participants achieving a 50% reduction compared to baseline in PASI score.

- Number of Participants With A PASI-90 Response at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-90 response indicates the number of participants achieving a 90% reduction compared to baseline in PASI score.

- Number of Participants With A PASI-100 Response at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-100 response indicates the number of participants achieving a 100% reduction compared to baseline in PASI score.

- Change From Baseline in Mean Participant Raw PASI Scores at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.

- Dermatology Life Quality Index (DLQI) at Week 28 [Time Frame: Week 28] [Designated as safety issue: No]

  The DLQI is a 10-item questionnaire. Scores range from 0-10 with 0 indicating high quality of life and 10 indicating poor quality of life.

- Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28 [Time Frame: Baseline, Week 28] [Designated as safety issue: No]

  The EQ-5D is a descriptive system comprised of the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants are asked to indicate his/her health state by selecting the most appropriate statement in each of the 5 dimensions. This selection results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1-5 have no arithmetic properties and should not be used as a cardinal score.

Enrollment:	39
Study Start Date:	October 2009
Study Completion Date:	April 2011
Primary Completion Date:	April 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: IFX q 6 weeks	Drug: Infliximab Infliximab 5 mg/kg body weight intravenous infusion given every 6 weeks Other Names: • Remicade • SCH 215596
Experimental: IFX + MTX	Drug: Infliximab and methotrexate Infliximab 5 mg/kg body weight intravenous infusion (given every 8 weeks) plus methotrexate 7.5 mg orally (once weekly)

	Other Names: • Remicade • SCH 215596

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Subjects must have a diagnosis of moderate to severe plaque-type psoriasis and have had participated in Study P05319.
- Subjects must have demonstrated an adequate but suboptimal response to infliximab in Study P05319
- Subjects must be at least 18 years old
- Subjects must be candidates for phototherapy or systemic treatment for psoriasis.
- Subjects must not be pregnant and must meet contraceptive requirements
- Subjects must meet tuberculosis screening criteria
- Subjects must meet laboratory and medical history screening requirements

Exclusion Criteria:

- Subjects for whom infliximab or methotrexate is contraindicated or not recommended.
- Subjects already using certain investigational, biological, or immunosuppressive drugs
- Subjects with certain comorbid conditions
- Subjects who currently have or have a history of certain infections
- Subjects who have recently received live virus or bacterial vaccinations
- 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.

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: NCT00833053 History of Changes
Other Study ID Numbers: P05315 EUDRACT: 2008-000454-12
Study First Received: January 29, 2009
Results First Received: March 15, 2012
Last Updated: August 13, 2015
Health Authority: United States: Institutional Review Board

Additional relevant MeSH terms:

Psoriasis	Antirheumatic Agents
Skin Diseases	Central Nervous System Agents
Skin Diseases, Papulosquamous	Dermatologic Agents
Antibodies, Monoclonal	Enzyme Inhibitors
Infliximab	Folic Acid Antagonists
Methotrexate	Gastrointestinal Agents

Abortifacient Agents
Abortifacient Agents, Nonsteroidal
Analgesics
Analgesics, Non-Narcotic
Anti-Inflammatory Agents
Anti-Inflammatory Agents, Non-Steroidal
Antimetabolites
Antimetabolites, Antineoplastic
Antineoplastic 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

ClinicalTrials.gov processed this record on April 10, 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

Dose Optimization of Infliximab in Moderate to Severe Plaque Psoriasis (Study P05315) (DOSE)

This study has been terminated.

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Information provided by (Responsible Party):
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ClinicalTrials.gov Identifier:
NCT00833053

First received: January 29, 2009
Last updated: August 13, 2015
Last verified: August 2015
History of Changes

Results First Received: March 15, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Psoriasis
Interventions:	Drug: Infliximab Drug: Infliximab and 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
Multicenter: 48 centers in Australia, Belgium, Colombia, Canada, Denmark, France, Germany, Greece, Hungary, Italy, and Russia.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 39 participants that were randomized to the study, 3 (2 Infliximab [IFX] q 6 weeks; and 1 IFX + Methotrexate [MTX]) participants did not meet protocol eligibility criteria and were excluded from the efficacy analysis.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Participant Flow: Overall Study

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
STARTED	19	20
COMPLETED	10	17
NOT COMPLETED	9	3
Adverse Event	4	0
Treatment Failure	3	1
Withdrawal by Subject	0	1
Protocol Violation	2	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
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.
Total	Total of all reporting groups

Baseline Measures

	IFX q 6 Weeks	IFX q 8 Weeks + MTX	Total
Number of Participants [units: participants]	17	19	36
Age [units: years] Mean (Standard Deviation)	45.3 (15.38)	48.2 (17.03)	46.8 (16.11)
Gender [units: participants]			
Female	5	5	10
Male	12	14	26

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Primary
Measure Title	Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28
Measure Description	The Psoriasis Area and Sensitivity Index (PASI) is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0–4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-75 response indicates the number of participants achieving a 75% reduction in PASI score compared to baseline.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	**IFX q 8 Weeks + MTX**
Number of Participants Analyzed [units: participants]	**17**	**19**
Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28 [units: Participants]	**9**	**11**

No statistical analysis provided for Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28

2. Secondary: Number of Participants With A PASI-50 Response at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With A PASI-50 Response at Week 28
Measure Description	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0–4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.The PASI-50 response indicates the number of participants achieving a 50% reduction compared to baseline in PASI score.

Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	**IFX q 8 Weeks + MTX**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With A PASI-50 Response at Week 28		

No statistical analysis provided for Number of Participants With A PASI-50 Response at Week 28

3. Secondary: Number of Participants With A PASI-90 Response at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With A PASI-90 Response at Week 28
Measure Description	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0–4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-90 response indicates the number of participants achieving a 90% reduction compared to baseline in PASI score.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once

	weekly.

Measured Values

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With A PASI-90 Response at Week 28		

No statistical analysis provided for Number of Participants With A PASI-90 Response at Week 28

4. Secondary: Number of Participants With A PASI-100 Response at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Number of Participants With A PASI-100 Response at Week 28
Measure Description	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0–4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-100 response indicates the number of participants achieving a 100% reduction compared to baseline in PASI score.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With A PASI-100 Response at Week 28		

No statistical analysis provided for Number of Participants With A PASI-100 Response at Week 28

5. Secondary: Change From Baseline in Mean Participant Raw PASI Scores at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Participant Raw PASI Scores at Week 28
Measure Description	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0–4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	**IFX q 8 Weeks + MTX**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change From Baseline in Mean Participant Raw PASI Scores at Week 28		

No statistical analysis provided for Change From Baseline in Mean Participant Raw PASI Scores at Week 28

6. Secondary: Dermatology Life Quality Index (DLQI) at Week 28 [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Dermatology Life Quality Index (DLQI) at Week 28
Measure Description	The DLQI is a 10-item questionnaire. Scores range from 0-10 with 0 indicating high quality of life and 10 indicating poor quality of life.
Time Frame	Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Number of Participants Analyzed [units: participants]	**0**	**0**
Dermatology Life Quality Index (DLQI) at Week 28		

No statistical analysis provided for Dermatology Life Quality Index (DLQI) at Week 28

7. Secondary: Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28 [Time Frame: Baseline, Week 28]

Measure Type	Secondary
Measure Title	Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28
Measure Description	The EQ-5D is a descriptive system comprised of the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants are asked to indicate his/her health state by selecting the most appropriate statement in each of the 5 dimensions. This selection results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1-5 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Week 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The study was terminated early with only 15% subjects of the original planned size. Accordingly, secondary efficacy analyses were cancelled due to such a small subject population.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Measured Values

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Number of Participants Analyzed [units: participants]	**0**	**0**

Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28		

No statistical analysis provided for Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety analyses were performed on all randomized subjects who took at least one dose of study medication.

Reporting Groups

	Description
IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Serious Adverse Events

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Total, serious adverse events		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
Skin and subcutaneous tissue disorders		
Psoriasis Aggravated [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**2**	**0**

1 Term from vocabulary, MedDRA (10.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety analyses were performed on all randomized subjects who took at least one dose of study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description

IFX q 6 Weeks	Infliximab 5 mg/kg administered every 6 weeks.
IFX q 8 Weeks + MTX	Infliximab 5mg/kg administered every 8 weeks in combination with methotrexate 7.5 mg orally once weekly.

Other Adverse Events

	IFX q 6 Weeks	IFX q 8 Weeks + MTX
Total, other (not including serious) adverse events		
# participants affected / at risk	**8/18 (44.44%)**	**6/19 (31.58%)**
Ear and labyrinth disorders		
Vertigo [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**2**	**0**
Gastrointestinal disorders		
Duodenal Ulcer [1]		
# participants affected / at risk	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Dyspepsia [1]		
# participants affected / at risk	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Nausea [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**1**	**0**
General disorders		
Chest Discomfort [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**1**	**0**
Infusion Related Reaction [1]		
# participants affected / at risk	**1/18 (5.56%)**	**1/19 (5.26%)**
# events	**1**	**1**
Infections and infestations		
Bronchitis [1]		
# participants affected / at risk	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Nasopharyngitis [1]		
# participants affected / at risk	**2/18 (11.11%)**	**0/19 (0.00%)**
# events	**2**	**0**
Oral Herpes [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**2**	**0**
Rash Pustular [1]		
# participants affected / at risk	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Renal Abscess [1]		

# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	1	0
Sinusitis [1]		
# participants affected / at risk	0/18 (0.00%)	2/19 (10.53%)
# events	0	4
Upper Respiratory Tract Infection [1]		
# participants affected / at risk	0/18 (0.00%)	1/19 (5.26%)
# events	0	1
Urinary Tract Infection [1]		
# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	1	0
Injury, poisoning and procedural complications		
Arthropod Sting [1]		
# participants affected / at risk	0/18 (0.00%)	1/19 (5.26%)
# events	0	1
Investigations		
Blood Pressure Increased [1]		
# participants affected / at risk	0/18 (0.00%)	1/19 (5.26%)
# events	0	1
Metabolism and nutrition disorders		
Hypercholesterolaemia [1]		
# participants affected / at risk	0/18 (0.00%)	1/19 (5.26%)
# events	0	1
Musculoskeletal and connective tissue disorders		
Muscle Spasm [1]		
# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	2	0
Nervous system disorders		
Hypotonia [1]		
# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	1	0
Reproductive system and breast disorders		
Vaginal Inflammation [1]		
# participants affected / at risk	0/18 (0.00%)	1/19 (5.26%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
Dyspnoea [1]		
# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	2	0
Oropharyngeal Pain [1]		
# participants affected / at risk	1/18 (5.56%)	0/19 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
[1]		

Pruritus		
# participants affected / at risk	**1/18 (5.56%)**	**1/19 (5.26%)**
# events	**1**	**1**
Pruritus Generalized [1]		
# participants affected / at risk	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**1**	**0**
Psoriasis [1]		
# participants affected / at risk	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**

1 Term from vocabulary, MedDRA (10.0)

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:

- [x] 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.

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

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00833053 History of Changes
Other Study ID Numbers: P05315
EUDRACT: 2008-000454-12

Study First Received:	January 29, 2009
Results First Received:	March 15, 2012
Last Updated:	August 13, 2015
Health Authority:	United States: Institutional Review Board

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