Remicade Study in Psoriatic Arthritis Patients Of Methotrexate-Naïve Disease (RESPOND) (Study P04422)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Integrated Therapeutics Group

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

ClinicalTrials.gov Identifier:
NCT00367237

First received: August 18, 2006
Last updated: May 27, 2015
Last verified: May 2015
History of Changes

Purpose

This study is undertaken to compare the efficacy and onset of action of infliximab plus methotrexate (IFX + MTX) versus methotrexate alone (MTX) in methotrexate naïve active psoriatic arthritis patients.

Condition	Intervention	Phase
Arthritis, Psoriatic	Drug: Infliximab + methotrexate (IFX + MTX) Drug: Methotrexate (MTX)	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 Randomized, Multicenter, International, Open-label Study of Infliximab Plus Methotrexate Versus Methotrexate (MTX) Alone for the Treatment of MTX naïve Subjects With Active Psoriatic Arthritis

Resource links provided by NLM:

Genetics Home Reference related topics: psoriatic arthritis

MedlinePlus related topics: Arthritis Psoriatic Arthritis

Drug Information available for: Methotrexate Methotrexate sodium Infliximab

Genetic and Rare Diseases Information Center resources: Spondylarthropathy

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16 [Time Frame: between baseline and week 16] [Designated as safety issue: No]

  >=20% improvement in swollen and tender joint count AND >=20% improvement in 3 of the following: visual analog scale (VAS) assessment of pain; subject VAS global assessment of disease activity; evaluator VAS global assessment of disease activity; Health Assessment Questionnaire (HAQ) disability index; C-Reactive Protein (CRP) level.

Secondary Outcome Measures:

- Proportion of Subjects Achieving ACR50, ACR70, and PASI75 if Applicable [Time Frame: between baseline and week 16] [Designated as safety issue: No]

  This is not a prespecified key secondary outcome; therefore, results will not be disclosed.

- Change in Disease Activity Score, Each of the ACR20 Domains, Dactylitis, Enthesitis, Fatigue and Duration of Morning Stiffness, Erythrocyte Sedimentation Rate, and Disability Index of the Health Assessment Questionnaire (HAQ) [Time Frame: between baseline and week 16] [Designated as safety issue: No]

  This is not a prespecified key secondary outcome; therefore, results will not be disclosed.

- Adverse Events [Time Frame: between baseline and week 16] [Designated as safety issue: Yes]

  This is not a prespecified key secondary outcome; therefore, results will not be disclosed.

Enrollment:	115
Study Start Date:	May 2006
Study Completion Date:	March 2008
Primary Completion Date:	March 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab + methotrexate (IFX + MTX) Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week	Drug: Infliximab + methotrexate (IFX + MTX) Infliximab 5 mg/kg infusion at Weeks 0, 2, 6, 14 and oral methotrexate 15 mg/week for 16 weeks. Methotrexate dose can be increased to 20 mg/week at week 6. Other Name: Group 1, Remicade + MTX
Active Comparator: Methotrexate (MTX) Oral methotrexate (MTX) 15 mg/week	Drug: Methotrexate (MTX) Oral methotrexate 15 mg/week for 15 weeks. Dose can be increased to 20 mg/week at Week 6. Other Name: Group 2, MTX

Eligibility

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

Criteria

Inclusion Criteria:

- The subject must meet ALL of the criteria listed below for entry into the study:
- Subject must demonstrate their willingness to participate in the study and comply with its procedures by signing a written informed consent.
- Subject aged 18 years or more, of either sex and any race
- Diagnosis of Psoriatic Arthritis with peripheral polyarticular involvement. Patients will have at least one of the following:

- Distal Interphalangeal Joints (DIP) involvement
- polyarticular arthritis, absence of rheumatoid nodules and presence of psoriasis
- arthritis mutilans
- asymmetric peripheral arthritis

- Negative rheumatoid factor
- The disease should have been diagnosed at least 3 months prior to screening.
- Active disease at the time of screening and prior to receiving the baseline study medication(s) as defined by:
  - 5 or more swollen joints and
  - 5 or more tender joints
  - and one out of the following three categories:
    - Erythrocyte Sedimentation Rate (ESR) >= 28 mm/h
    - C-reactive protein (CRP) >= 15 mg/l
    - Morning stiffness >= 45 min
- Subjects must confirm that they are practicing adequate contraception: Female subjects of childbearing potential (includes women who are less than 1 year postmenopausal and women who become sexually active during the study) must agree to use a medically accepted method of contraception or be surgically sterilized prior to screening, while receiving protocol-specified medication, and for 6 months after stopping the medication. Acceptable methods of contraception include condoms (male and female) with or without a spermicidal agent, diaphragm or cervical cap with spermicide, medically prescribed intrauterine device (IUD), oral or injectable hormonal contraceptive, and surgical sterilization (e.g., hysterectomy or tubal ligation).
- Female subjects of childbearing potential must have a negative pregnancy test at Screening.
- Subjects must be eligible for anti-tumor necrosis factor (TNF) treatment according to applicable local guidelines. For all patients chest X-ray and skin test results must be available at baseline.
- If using Nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids other than i.v., i.m. or i.a., the patient must be on a stable dose for four weeks prior screening (maximum dose up to 10mg/day of prednisone or its oral equivalent).
- The screening laboratory tests must beet the following criteria:
  - Hemoglobin >= 10 g/dl providing the low hemoglobin level is not due to other diseases than anemia of chronic inflammation.
  - white blood cell (WBC) >= 3500 / µl
  - Neutrophils >= 1500 / µl
  - Platelets >= 100 000/ µl
  - Aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma-glutamyltransferase <= 1.5 x upper limit of normal
  - Total bilirubin <= 1 x upper limit of normal
  - Serum creatinine <= 1.5 mg/dl
- Patient must be able to adhere to the study visit schedule and other protocol requirements and must have given informed consent prior to any screening procedures.

Exclusion Criteria:

- The subject will be excluded from entry into the study if ANY of the criteria listed below are met:
- Subject is a female who is pregnant, intends to become pregnant during the study (or within 6 months after study completion), or nursing.
- Patients with other inflammatory diseases that might interfere with the evaluation of the psoriatic arthritis.
- Previous treatment with Infliximab.
- Subjects who have previously received MTX or have not discontinued their other DMARD therapy (i.e., sulfasalazine, hydroxychloroquine, leflunomide).
- Patients with fibromyalgia syndrome.
- Use of cyclosporine or tacrolimus within 4 weeks prior to screening. Use of IM, IV, or IA corticosteroids within 4 weeks prior to screening.
- Treatment with any investigational drug within 3 months prior to screening.
- Previous treatment with a monoclonal antibody or a fusion protein.
- A history of known allergy to murine proteins.
- History of infected joint prosthesis within the previous 5 years.
- Chronic infections.
- History of active tuberculosis requiring treatment within previous 3 years or history of opportunistic infections within 2 months, uncontrolled active infection or documented HIV infection. Also excluded are patients with evidence of latent tuberculosis and patients with old tuberculosis without documented adequate therapy, if they will not be treated according to local tuberculosis (TB) guidelines.
- Subject has any clinically significant deviation from normal in the physical examination, chest X-ray, or electrocardiogram (ECG) that, in the

investigator's judgment, may interfere with the study evaluation or affect subject safety.

- Current signs or symptoms of other severe uncontrolled diseases, which in the investigators opinion would put the patient at an unacceptable risk.
- History of lymphoproliferative disease, any current malignancies or history of malignancy within 5 years other than successfully treated basal cell carcinoma or squamous cell carcinoma of the skin.
- Subject is part of the staff or a family member of the staff personnel directly involved with this study.
- History of drug abuse.
- Subjects who are participating in any other clinical 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 by Merck Sharp & Dohme Corp.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Baranauskaite A, Raffayová H, Kungurov NV, Kubanova A, Venalis A, Helmle L, Srinivasan S, Nasonov E, Vastesaeger N; RESPOND investigators. Infliximab plus methotrexate is superior to methotrexate alone in the treatment of psoriatic arthritis in methotrexate-naive patients: the RESPOND study. Ann Rheum Dis. 2012 Apr;71(4):541-8. doi: 10.1136/ard.2011.152223. Epub 2011 Oct 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00367237 History of Changes
Other Study ID Numbers:	P04422 EUDRACT #: 2005-002189-12
Study First Received:	August 18, 2006
Results First Received:	March 19, 2009
Last Updated:	May 27, 2015
Health Authority:	Russia: Pharmacological Committee, Ministry of Health Estonia: The State Agency of Medicine Lithuania: State Medicine Control Agency - Ministry of Health Egypt: Ministry of Health and Population Israel: Israeli Health Ministry Pharmaceutical Administration Poland: Ministry of Health Slovakia: State Institute for Drug Control Hungary: National Institute of Pharmacy Romania: State Institute for Drug Control Bulgaria: Ministry of Health Croatia: Ministry of Health and Social Care Slovenia: Agency for Medicinal Products - Ministry of Health Turkey: Ministry of Health South Africa: National Health Research Ethics Council Qatar: Hamad Medical Corporation, Rheumatology Divison-Doha

Additional relevant MeSH terms:

Arthritis	Abortifacient Agents, Nonsteroidal
Arthritis, Psoriatic	Analgesics
Bone Diseases	Analgesics, Non-Narcotic
Joint Diseases	Anti-Inflammatory Agents
Musculoskeletal Diseases	Anti-Inflammatory Agents, Non-Steroidal
Psoriasis	Antimetabolites
Skin Diseases	Antimetabolites, Antineoplastic
Skin Diseases, Papulosquamous	Antineoplastic Agents
Spinal Diseases	Antirheumatic Agents
Spondylarthritis	Central Nervous System Agents

Spondylarthropathies
Spondylitis
Infliximab
Methotrexate
Abortifacient Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Gastrointestinal Agents
Immunologic Factors

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: March 19, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Arthritis, Psoriatic
Interventions:	Drug: Infliximab + methotrexate (IFX + MTX) Drug: Methotrexate (MTX)

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
115 subjects (57 infliximab (IFX) + MTX and 58 MTX), but only 110 subjects (56 and 54) were considered intent to treat (ITT). Furthermore, 99 subjects (51 + 48) were in a treatment group at Week 16 for Primary Endpoint evaluation.

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 + Methotrexate (IFX + MTX)	Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week
Methotrexate (MTX)	Oral methotrexate (MTX) 15 mg/week

Participant Flow: Overall Study

	Infliximab + Methotrexate (IFX + MTX)	Methotrexate (MTX)
STARTED	**57** [1]	**58** [1]
COMPLETED	**47**	**47**
NOT COMPLETED	**10**	**11**
Adverse Event	**7**	**2**
Lost to Follow-up	**1**	**0**
Withdrawal by Subject	**0**	**4**
Protocol Violation	**2**	**5**

[1] Number of subjects randomized

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 + Methotrexate (IFX + MTX)	Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week
Methotrexate (MTX)	Oral methotrexate (MTX) 15 mg/week
Total	Total of all reporting groups

Baseline Measures

	Infliximab + Methotrexate (IFX + MTX)	Methotrexate (MTX)	Total
Number of Participants [units: participants]	**56**	**54**	**110**
Age [1] **[units: years] Mean (Full Range)**	**40.1 (20 to 65)**	**42.3 (21 to 65)**	**41.2 (20 to 65)**
Gender [units: participants]			

Female	**29**	**21**	**50**
Male	**27**	**33**	**60**

[1] ITT population

Outcome Measures

1. Primary: Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16 [Time Frame: between baseline and week 16]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16
Measure Description	>=20% improvement in swollen and tender joint count AND >=20% improvement in 3 of the following: visual analog scale (VAS) assessment of pain; subject VAS global assessment of disease activity; evaluator VAS global assessment of disease activity; Health Assessment Questionnaire (HAQ) disability index; C-Reactive Protein (CRP) level.
Time Frame	between baseline and week 16
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.
Number of subjects from Intent-to-Treat population in each arm at Week 16

Reporting Groups

	Description
Infliximab + Methotrexate (IFX + MTX)	Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week
Methotrexate (MTX)	Oral methotrexate (MTX) 15 mg/week

Measured Values

	Infliximab + Methotrexate (IFX + MTX)	**Methotrexate (MTX)**
Number of Participants Analyzed [units: participants]	**51**	**48**
Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16 [units: participants]	**44**	**32**

Statistical Analysis 1 for Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16

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

P Value [3]	0.0210
Difference in percentages of respondents [4]	19.61
95% Confidence Interval	3.27 to 35.95

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Comparison of treatments (IFX + MTX versus MTX)
[4]	Other relevant estimation information:
	Difference in percentages of respondents is (percentage of respondents in IFX+MTX group minus percentage of respondents in MTX group)

Statistical Analysis 2 for Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16

Groups [1]	Infliximab + Methotrexate (IFX + MTX)
Proportion of Responders [2]	0.863

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Number of Subjects Achieving ACR20 (at Least 20% Improvement in American College of Rheumatology Criteria From Baseline) at Week 16

Groups [1]	Methotrexate (MTX)
Proportion of Responders [2]	0.667

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

2. Secondary: Proportion of Subjects Achieving ACR50, ACR70, and PASI75 if Applicable [Time Frame: between baseline and week 16]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

3. Secondary: Change in Disease Activity Score, Each of the ACR20 Domains, Dactylitis, Enthesitis, Fatigue and Duration of Morning Stiffness, Erythrocyte Sedimentation Rate, and Disability Index of the Health Assessment Questionnaire (HAQ) [Time Frame: between baseline and week 16]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

4. Secondary: Adverse Events [Time Frame: between baseline and week 16]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** Yes

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety analyses included all subjects who received at least 1 dose of study medication Subjects were questioned and/or examined by the investigator for evidence of adverse events. The questioning of subjects with regard to the possible occurrence of adverse events were to be generalized such as, “How have you been feeling since your last visit?”

Reporting Groups

	Description
Infliximab + Methotrexate (IFX + MTX)	Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week
Methotrexate (MTX)	Oral methotrexate (MTX) 15 mg/week

Serious Adverse Events

	Infliximab + Methotrexate (IFX + MTX)	Methotrexate (MTX)
Total, serious adverse events		
# participants affected / at risk	**2/57 (3.51%)**	**0/54 (0.00%)**
General disorders		
Infusion related reaction † 1		
# participants affected / at risk	**1/57 (1.75%)**	**0/54 (0.00%)**
# events	**1**	**0**
Infections and infestations		
Pulmonary Tuberculosis † 1		
# participants affected / at risk	**1/57 (1.75%)**	**0/54 (0.00%)**
# events	**1**	**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	Safety analyses included all subjects who received at least 1 dose of study medication Subjects were questioned and/or examined by the investigator for evidence of adverse events. The questioning of subjects with regard to the possible occurrence of adverse events were to be generalized such as, “How have you been feeling since your last visit?”

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Infliximab + Methotrexate (IFX + MTX)	Remicade (infliximab [IFX]) 5 mg/kg infusions at Weeks 0, 2, 6, 14 and oral methotrexate (MTX) 15 mg/week
Methotrexate (MTX)	Oral methotrexate (MTX) 15 mg/week

Other Adverse Events

	Infliximab + Methotrexate (IFX + MTX)	Methotrexate (MTX)
Total, other (not including serious) adverse events		
# participants affected / at risk	**12/57 (21.05%)**	**10/54 (18.52%)**
Gastrointestinal disorders		
Abdominal Pain Upper † 1		
# participants affected / at risk	**0/57 (0.00%)**	**3/54 (5.56%)**
# events	**0**	**3**
Investigations		
Alanine Aminotransferase Increased † 1		
# participants affected / at risk	**6/57 (10.53%)**	**5/54 (9.26%)**
# events	**6**	**5**
Blood Bilirubin Increased † 1		
# participants affected / at risk	**2/57 (3.51%)**	**3/54 (5.56%)**
# events	**2**	**3**
Transaminases Increased † 1		
# participants affected / at risk	**3/57 (5.26%)**	**1/54 (1.85%)**
# events	**4**	**1**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**3/57 (5.26%)**	**1/54 (1.85%)**
# events	**3**	**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:** Investigator must provide 30 days written notice to sponsor prior to submission for publication/presentation, so that sponsor can review the material(s). If the parties disagree concerning the appropriateness of the material for publication, the investigator must meet with sponsor prior to publication/presentation, in order to make good faith efforts to discuss and resolve any disagreements.

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 by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Baranauskaite A, Raffayová H, Kungurov NV, Kubanova A, Venalis A, Helmle L, Srinivasan S, Nasonov E, Vastesaeger N; RESPOND investigators. Infliximab plus methotrexate is superior to methotrexate alone in the treatment of psoriatic arthritis in methotrexate-naive patients: the RESPOND study. Ann Rheum Dis. 2012 Apr;71(4):541-8. doi: 10.1136/ard.2011.152223. Epub 2011 Oct 12.

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Qatar: Hamad Medical Corporation, Rheumatology Divison-Doha

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