Induction of Remission in RA Patients at Low Disease Activity by Additional Infliximab Therapy (Study P04644AM1) (TERMINATED)

This study has been terminated.
(Slow Enrollment)

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
AESCA Pharma GmbH

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

ClinicalTrials.gov Identifier:
NCT00521924

First received: August 27, 2007
Last updated: March 18, 2015
Last verified: March 2015
History of Changes

Purpose

This Phase 3, randomized, open-label, multicenter study in rheumatoid arthritis (RA) patients with low disease activity (Disease Activity Score 28 [DAS28] >2.8 and <3.5) is being conducted to evaluate induction of remission by adding infliximab to pre-existing treatment versus no additional treatment. All subjects eligible for this study, aged >35 to <=65 years, will have a diagnosis of RA according to American College of Rheumatology (ACR) criteria, and will be offered additional treatment with infliximab. Prior to the start of treatment, subjects must be on a stable regimen of disease modifying antirheumatic drugs (DMARDs) for at least 3 months. Subjects will be randomized (1:1) to basic therapy with or without infliximab for a total duration of 38 weeks followed by a follow-up period of up to 6 months. Subjects randomized to basic therapy + infliximab will receive infliximab 3 mg/kg at Weeks 0, 2, 6, 14, 22, 30, and 38. The primary objective of the study is to assess the rate of remission according to DAS 28 (<2.6) at the end of treatment (after 38 weeks). Safety assessments include the incidence of adverse events, serious adverse events, and clinically notable abnormal vital signs and laboratory values.

Condition	Intervention	Phase
Rheumatoid Arthritis	Biological: infliximab Drug: DMARDs (methotrexate; chloroquine; leflunomidum; cyclosporin A; sulfasalazine; OM 89.	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: Induction of Remission in RA Patients at Low Disease Activity by Additional Infliximab-therapy

Resource links provided by NLM:

Genetics Home Reference related topics: rheumatoid arthritis

MedlinePlus related topics: Arthritis Rheumatoid Arthritis

Drug Information available for: Chloroquine phosphate Chloroquine Methotrexate Chloroquine sulfate Sulfasalazine Chloroquine hydrochloride Methotrexate sodium Cyclosporine Cyclosporin Infliximab

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Patients in Remission According to Disease Activity Score (DAS) 28 (< 2.6) [Time Frame: after 38 weeks] [Designated as safety issue: No]

  The DAS 28 is an assessment of disease activity based on swollen joint count, erythrocyte sedimentation rate, and general health. Patients can be scored on a range of 0 to 10, with lower scores indicating less disease activity.

Secondary Outcome Measures:

- DAS 28 at Baseline vs at Week 38; Quality of Life; American College of Rheumatology (ACR) Response Disease Progression (X-ray); Effect of Inflammatory Markers on Response and Disease Progression; Assess Simplified Disease Activity Index (SDAI). [Time Frame: Weeks 14, 38, and 62] [Designated as safety issue: No]

  These were not prespecified key secondary outcomes; therefore, results will not be disclosed.

Enrollment:	8
Study Start Date:	June 2007
Study Completion Date:	April 2008
Primary Completion Date:	April 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Infliximab + basic treatment 3 mg/kg infliximab plus basic treatment	Biological: infliximab infliximab 3 mg/kg and basic treatment Other Name: Basic treatment for RA (DMARDs)
Active Comparator: Basic treatment (DMARDs) Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])	Drug: DMARDs (methotrexate; chloroquine; leflunomidum; cyclosporin A; sulfasalazine; OM 89. Methotrexate (15 - 25 mg/week); chloroquine; leflunomidum; cyclosporin A; sulfasalazine; OM 89

Eligibility

Ages Eligible for Study:	19 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients aged >35 and <=65 years with a diagnosis of rheumatoid arthritis (RA) according to American College of Rheumatology (ACR) criteria for at least 1 year and no more than 10 years prior to start of therapy; have active disease (Disease Activity Score [DAS] 28 >2.8 and <3.5), with changes in the DAS 28 score <0.6 within the 6 weeks before inclusion; have stable RA basic therapy according to standard criteria for at least 3 months; have a chest X-ray within 1 month prior to first infusion with no evidence of malignancy, infections, or fibrosis; and have screening laboratory test results that meet prespecified criteria. Patient must have at least one swollen joint. Patient must have evidence of erosive disease by x-ray at baseline.

Exclusion Criteria:

- Patients were excluded if they met any of the following criteria:
  - Women who are pregnant, nursing, or planning pregnancy within 15 months after screening (i.e., approximately 6 months following last infusion);
  - Use of any investigational drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer;
  - History of any other therapeutic agent targeted at reducing tumor necrosis factor (TNF);
  - History of previous administration of infliximab;
  - History of receiving human/murine recombinant products or has a known allergy to murine products;
  - Serious infection (such as hepatitis, pneumonia or pyelonephritis) in the previous 3 months. Less serious infections (such as acute upper respiratory tract infection [colds] or simple urinary tract infection) need not be considered exclusions at the discretion of the investigator.
  - Active tuberculosis (TB) or evidence of latent TB (positive purified protein derivative [PPD] skin test, a history of old or latent TB or chest X-ray without adequate therapy for TB initiated prior to first infusion of study drug), or evidence of an old or latent TB infection without documented adequate therapy. Patients with a current close contact with an individual with active TB and patients who have completed treatment for active TB within the previous 2 years are explicitly excluded from the trial. Patients with a household member who has a history of active pulmonary TB should have had a thorough evaluation for TB prior to study enrollment as recommended by a local infectious disease specialist or published local guidelines of TB control agencies.
  - Hepatitis B surface antigen or Hepatitis C (HCV) antibody positive; documented Human Immunodeficiency Virus (HIV) infection;
  - Have an opportunistic infection, including but not limited to evidence of active cytomegalovirus, active pneumocystis carinii, aspergillosis, or atypical mycobacterium infection, etc, within the previous 6 months;
  - Have current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, psychiatric, neurologic, or cerebral disease (including demyelinating diseases such as multiple sclerosis);
  - Concomitant congestive heart failure >= New York Heart Association (NYHA) II;
  - Have a transplanted organ (with the exception of a corneal transplant >3 months prior to screening);
  - Fibromyalgia;
  - Malignancy within the past 5 years (except for squamous or basal cell carcinoma of the skin that has been treated with no evidence of recurrence);
  - History of lymphoproliferative disease including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location (such as nodes in the posterior triangle of the neck, infraclavicular, epitrochlear, or peri-aortic areas), or splenomegaly; or
  - Known recent substance abuse (drug or alcohol).

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:	NCT00521924 History of Changes
Other Study ID Numbers:	P04644 2005-004530-40
Study First Received:	August 27, 2007
Results First Received:	April 3, 2009
Last Updated:	March 18, 2015
Health Authority:	Austria: AGES Austria: GmbH

Additional relevant MeSH terms:

Arthritis, Rheumatoid	Abortifacient Agents, Nonsteroidal
Arthritis	Amebicides
Autoimmune Diseases	Analgesics
Connective Tissue Diseases	Analgesics, Non-Narcotic
Immune System Diseases	Anti-Infective Agents

Joint Diseases	Anti-Inflammatory Agents
Musculoskeletal Diseases	Anti-Inflammatory Agents, Non-Steroidal
Rheumatic Diseases	Antifungal Agents
Chloroquine	Antimalarials
Cyclosporine	Antimetabolites
Cyclosporins	Antimetabolites, Antineoplastic
Infliximab	Antineoplastic Agents
Methotrexate	Antiparasitic Agents
Sulfasalazine	Antiprotozoal Agents
Abortifacient Agents	Antirheumatic Agents

ClinicalTrials.gov processed this record on April 10, 2016

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History of Changes

Results First Received: April 3, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Rheumatoid Arthritis
Interventions:	Biological: infliximab Drug: DMARDs (methotrexate; chloroquine; leflunomidum; cyclosporin A; sulfasalazine; OM 89.

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

Due to poor enrollment rate, this trial was terminated prematurely. Eight patients had been enrolled from June 2007 to April 2008: 4 in each arm.

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 + Basic Treatment	3 mg/kg infliximab plus basic treatment
Basic Treatment (DMARDs)	Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])

Participant Flow: Overall Study

	Infliximab + Basic Treatment	Basic Treatment (DMARDs)
STARTED	**4** [1]	**4** [1]
COMPLETED	**0** [2]	**0** [3]
NOT COMPLETED	**4**	**4**

[1] Subjects randomized
[2] At Early Termination, 1 patient completed Week 2 and 2 patients completed Week 6.
[3] At Early Termination, 3 patients completed Week 6 and 1 completed Week 22.

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 + Basic Treatment	3 mg/kg infliximab plus basic treatment
Basic Treatment (DMARDs)	Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])
Total	Total of all reporting groups

Baseline Measures

	Infliximab + Basic Treatment	Basic Treatment (DMARDs)	Total
Number of Participants [units: participants]	**4**	**4**	**8**
Age, Customized [units: participants]	**4**	**4**	**8**
Gender [units: participants]			
Female	**4**	**1**	**5**
Male	**0**	**3**	**3**

Outcome Measures

1. Primary: Number of Patients in Remission According to Disease Activity Score (DAS) 28 (< 2.6) [Time Frame: after 38 weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Number of Patients in Remission According to Disease Activity Score (DAS) 28 (< 2.6)
Measure Description	The DAS 28 is an assessment of disease activity based on swollen joint count, erythrocyte sedimentation rate, and general health. Patients can be scored on a range of 0 to 10, with lower scores indicating less disease activity.
Time Frame	after 38 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.
This trial terminated early due to poor enrollment. Since none of the randomized patients reached Week 38, no change of DAS28 between baseline and Week 38 could be analyzed.

Reporting Groups

	Description
Infliximab + Basic Treatment	3 mg/kg infliximab plus basic treatment
Basic Treatment (DMARDs)	Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])

Measured Values

	Infliximab + Basic Treatment	**Basic Treatment (DMARDs)**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Patients in Remission According to Disease Activity Score (DAS) 28 (< 2.6)		

No statistical analysis provided for Number of Patients in Remission According to Disease Activity Score (DAS) 28 (< 2.6)

2. Secondary: DAS 28 at Baseline vs at Week 38; Quality of Life; American College of Rheumatology (ACR) Response Disease Progression (X-ray); Effect of Inflammatory Markers on Response and Disease Progression; Assess Simplified Disease Activity Index (SDAI). [Time Frame: Weeks 14, 38, and 62]

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text

	entered.
Additional Description	No text entered.

Reporting Groups

	Description
Infliximab + Basic Treatment	3 mg/kg infliximab plus basic treatment
Basic Treatment (DMARDs)	Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])

Serious Adverse Events

	Infliximab + Basic Treatment	Basic Treatment (DMARDs)
Total, serious adverse events		
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**

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 + Basic Treatment	3 mg/kg infliximab plus basic treatment
Basic Treatment (DMARDs)	Rheumatoid Arthritis basic therapy (disease modifying anti-rheumatic drugs [DMARDs])

Other Adverse Events

	Infliximab + Basic Treatment	Basic Treatment (DMARDs)
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**

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:** Principal Investigator (PI) has the right to publish/publicly present the results of the Study, but may not to publish/publicly present any interim results. PI must provide 45 days written notice to Sponsor prior to submission for publication/presentation to permit Sponsor to review drafts for publication which report any results arising out of the Study. Sponsor shall have the right to review and comment on any Public Presentation.

Results Point of Contact:

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

No publications provided

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Other Study ID Numbers:	P04644 2005-004530-40
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Health Authority:	Austria: AGES Austria: GmbH

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