

# Prospective study on the effects of adalimumab treatment in patients with rheumatoid arthritis

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Prospective study on the effects of adalimumab treatment in patients with rheumatoid arthritis

## Acronym

adalimumab

## Study objectives

To evaluate the response to adalimumab treatment in Tumour Necrotising Factor (TNF)-alpha blockade naïve patients and patients who failed prior other anti-TNF-alpha treatment and to understand the mechanisms underlying the clinical response to TNF-alpha blockade.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Medical ethical committee of the Academic Medical Center /University of Amsterdam on the 12/02/2004 (ref: MEC04/007)

## Study design

Single-centre open-label prospective, exploratory phase IV study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Rheumatoid arthritis

## Interventions

Adalimumab 40 mg subcutaneously once every two weeks.

## Intervention Type

Drug

## Phase

Phase IV

**Drug/device/biological/vaccine name(s)**

Adalimumab

**Primary outcome measure**

1. Clinical efficacy according to the European League Against Rheumatism (EULAR) response criteria at week 16 after initiation of treatment
2. Exploration of clinical and serological markers that might distinguish responding from non-responding patients (e.g. the influence of anti-adalimumab antibody formation and adalimumab concentrations on response)

**Secondary outcome measures**

1. Clinical efficacy according to the EULAR response criteria at week 40 and 52 after initiation of treatment
2. Exploration of genetic markers (e.g. cytokine polymorphisms) that are associated with clinical efficacy
3. The effects of adalimumab on bone mineral density as measured by Dual Energy X-ray Absorptiometry (DEXA) scanning
4. The effects of adalimumab on lipid metabolism as measured by fasting serum lipid profiles in time
5. The effects of adalimumab on work productivity and sick leave measured by work-related questionnaires during 52 weeks follow-up

**Overall study start date**

07/04/2004

**Completion date**

07/04/2005

**Eligibility****Key inclusion criteria**

1. Patients with the diagnosis rheumatoid arthritis according to the American Rheumatism Association (ARA) 1987 criteria and in American College of Rheumatology (ACR) 1991 functional classes I, II, and III
2. The patient is naïve for anti-TNF-alpha therapy or has failed other prior TNF-alpha blockers
3. Disease Activity Score (DAS 28) more than or equal to 3.2
4. Age 18 to 85 years old
5. Use concurrent methotrexate treatment (5 - 30 mg/week stable since at least 28 days before initiation) during the study. Subjects may be taking nonsteroidal anti-inflammatory drugs, provided the dose and frequency have been stable for at least 28 days. Subjects may be receiving prednisone therapy less than or equal to 10 mg/day provided that the dosage has been stable for at least two months prior to entry

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

50

**Key exclusion criteria**

1. Pregnancy
2. Breastfeeding
3. A history of or current acute inflammatory joint disease of different origin e.g. mixed connective tissue disease, seronegative spondylarthropathy, psoriatic arthritis, Reiter's syndrome, systemic lupus erythematosus or any arthritis with onset prior to age 16 years
4. Acute major trauma
5. Therapy within the previous 60 days with:
  - a. any experimental drug
  - b. alkylating agents
  - c. antimetabolites
  - d. monoclonal antibodies (including infliximab and etanercept)
  - e. growth factors
  - f. other cytokines
6. Therapy within the previous 28 days with:
  - a. parenteral or intra-articular corticoid injections
  - b. oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily
  - c. present use of Disease Modifying Anti-Rheumatic Drugs (DMARDs) other than methotrexate
7. Receipt of any live (attenuated) vaccines within four weeks prior to baseline
8. Fever (orally measured more than 38°C), chronic infections or infections requiring anti-microbial therapy
9. Known positive reaction to hepatitis B surface antigen or hepatitis C antigen
10. Other active medical conditions such as inflammatory bowel disease, bleeding diathesis, or severe unstable diabetes mellitus
11. Manifest cardiac failure (stage III or IV according to New York Heart Association [NYHA] classification)
12. Progressive fatal disease/terminal illness
13. A congenital or acquired (known Human Immunodeficiency Virus [HIV]-positive status) immunodeficiency
14. A history of lymphoproliferative disease or treatment with total lymphoid irradiation
15. A white cell count less than  $3.5 \times 10^9/l$
16. Platelet count less than  $100 \times 10^9/l$
17. Haemoglobin of less than 5.3 mmol/l
18. Body weight of less than 45 kg
19. History of drug or alcohol abuse
20. Any concomitant medical condition which would in the investigator's opinion compromise the patient's ability to tolerate, absorb, metabolise or excrete the study medication
21. Inability to give informed consent
22. Mental condition rendering the patient unable to understand the nature, scope and possible consequences of the study and/or evidence of an uncooperative attitude

**Date of first enrolment**

07/04/2004

**Date of final enrolment**

07/04/2005

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

**Academic Medical Center (AMC)**

Amsterdam

Netherlands

1100 DD

# Sponsor information

## Organisation

Academic Medical Center

## Sponsor details

Division of Clinical Immunology and Rheumatology

PO Box 22660

Amsterdam

Netherlands

1100 DD

## Sponsor type

Hospital/treatment centre

## Website

<http://www.amc.uva.nl/>

## ROR

<https://ror.org/03t4gr691>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Academic Medical Center (AMC) (The Netherlands)

## Alternative Name(s)

Academic Medical Center, AMC

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

Netherlands

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2008	06/01/2021	Yes	No