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

Submission date	Recruitment status	[ ] Prospectively registered
22/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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 Absortiometry (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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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 x 10^9/l
16. Platelet count less than 100 x 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

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

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?
Results article	results	01/04/2008	06/01/2021	Yes	No