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

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To evaluate the response to adalimumab treatment in 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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20706

Bron
NTR

Verkorte titel
adalimumab

Aandoening

Rheumatoid arthritis

Ondersteuning

Primaire sponsor: AMC, Division of Clinical Immunology & Rheumatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoints:

1. Clinical efficacy according to the 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).

Toelichting onderzoek

Achtergrond van het onderzoek

Monocenter open label prospective, exploratory phase IV study into the effects of adalimumab treatment in patients with rheumatoid arthritis that are starting treatment with a TNF blocker as part of routine patient care. The patients have never before received TNF blockade or failed prior TNF blocking therapy.

A total of 50 patiënts with rheumatoid arthritis will be included and treated with adalimumab 40 mg/2wks s.c. and followed up until week 52. Clinical efficacy parameters will be measured every 12 weeks from baseline.

Factors influencing clinical efficacy of adalimumab will be studied. Furthermore the effect of adalimumab on lipidmetabolism, bonemineraldensity and workproductivity will be determined.

Doel van het onderzoek

To evaluate the response to adalimumab treatment in 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.

Onderzoeksproduct en/of interventie

Adalimumab 40mg subcutaneously 1x/2 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with the diagnosis rheumatoid arthritis according to the American Rheumatism Association (ARA) 1987 criteria and in 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. DAS 28 => 3.2;
4. Age 18 - 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 <= 10 mg/day rovided that the dosage has been stable for at least 2 months prior to entry.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 intraarticular corticoid injections;
b. Oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily;
c. Present use of DMARDs other than methotrexate;
7. Receipt of any live (attenuated) vaccines within 4 weeks prior to baseline;
8. Fever (orally measured > 38 ¢XC), 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 NYHA classification);
12. Progressive fatal disease/terminal illness;
13. A congenital or acquired (known 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 109/l;
16. Platelet count less than 100 x 109/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, metabolize 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-04-2004
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-12-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL843
NTR-old	NTR857
Ander register	: N/A
ISRCTN	ISRCTN68762628

Resultaten

Samenvatting resultaten

N/A