Etanercept cohort studie.

Gepubliceerd: 02-08-2010 Laatst bijgewerkt: 18-08-2022

Previous randomised trials have shown the efficacy of etanercept in RA patients. In this study we will evaluate the respons of etanercept in anti-TNF naive patients compared to patients who have failed other anti-TNF. We will look for clinical...

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

Samenvatting

ID

NL-OMON26481

Bron
NTR

Verkorte titel
Etanercept cohort studie

Aandoening

RA, Reumatoide Artritis, Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum Div. Immunology and Rheumatology
Overige ondersteuning: Academisch Medisch Centrum Div. Immunology and Rheumatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is the percentage of patients with a moderate to good response to etanercept treatment at 16 weeks according to the Eular response criteria which is also applied in routine rheumatological practice.

Furthermore the primary endpoint of the study is to search for clinical parameters and/or serological markers that possibly distinguish responders from non-responders to TNF-α blockade by etanercept.

Toelichting onderzoek

Achtergrond van het onderzoek

A monocenter prospective, exploratory study with a 2 to 4-week screening period and a 52-week follow-up period in 200 RA patients who receive etanercept treatment in routine rheumatological practice and are TNF-alpha blockade naïve or have failed to (or no longer) respond to other anti-TNF-alpha treatment. There is no group of patients receiving control treatment, since it is considered unethical to withhold active treatment for 52 weeks in patients with active RA.

Recruitment in the Netherlands.

Doel van het onderzoek

Previous randomised trials have shown the efficacy of etanercept in RA patients. In this study we will evaluate the respons of etanercept in anti-TNF naive patients compared to patients who have failed other anti-TNF. We will look for clinical parameters and serological markers that may differentiate responders from non-responders on etanercept.

Onderzoeksopzet

Week 0, 4, 16, 28, 40 and 52.

Onderzoeksproduct en/of interventie

Study medication and dosage:

1. Etanercept EU/1*99/126/001;

2. Dosage: 50 mg by subcutaneous injection every week.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Wetenschappelijk

Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

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. Failure on two previously used DMARDs;

5. Age > 18 and =< 85 years old;

6. 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 provided that the dosage has been stable for at least 28 days 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, e.g. cyclophosphamide, chlorambucil;

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 °C), chronic infections or infections requiring anti-microbial therapy;

9. Other active medical conditions such as inflammatory bowel disease, bleeding diathesis, or severe unstable diabetes mellitus;

10. Manifest cardiac failure (stage III or IV according to NYHA classification);

11. Progressive fatal disease/terminal illness;

12. A history of lymphoproliferative disease or treatment with total lymphoid irradiation;

13. A white cell count less than 3.5 x 109/l;

14. Platelet count less than 100 x 109/l;

15. Haemoglobin of less than 5.3 mmol/l;

16. Body weight of less than 45 kg;

17. History of drug or alcohol abuse;

18. 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;

19. Inability to give informed consent;

20. 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:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-08-2010
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	NL2336
NTR-old	NTR2443
Ander register	MEC AMC / EudraCT : 09-249 / 2009-015653-20 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A