Etanercept cohort studie.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26481

Source
NTR

Brief title
Etanercept cohort studie

Health condition

RA, Reumatoide Artritis, Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Div. Immunology and Rheumatology
Source(s) of monetary or material Support: Academisch Medisch Centrum Div. Immunology and Rheumatology

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secundary endpoint of the study is the proportion of patients with a 20%, 50%, and 70% clinical improvement according to the ACR response criteria [13] at 4, 16, 28, 40 and 52 weeks after the initiation of etanercept treatment. The parameters of disease activity e.g. tender joint count, swollen joint count, patient's assessment of pain, patient's global assessment, investigators global assessment, duration of morning stiffness, health assessment questionnaire, DAS 28, SF-36 (short form health survey) and RADAI [14] will be assessed at each time point starting from baseline.

We will look for genetic markers, e.g. genetic polymorphisms in TNF-alpha genes, that may predict diagnosis, efficacy and side-effects of treatment in the individual patient.

In the future micro-array analysis may be done to screen for new markers that distinguish responders from non-responders.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

Study medication and dosage:

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

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

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, 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010

Enrollment:	200
Type:	Actual

Ethics review

Positive opinion Date:	02-08-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2336
NTR-old	NTR2443
Other	MEC AMC / EudraCT : 09-249 / 2009-015653-20 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A