Exploratory trial on intra-articular etanercept treatment in inflammatory arthritis

No registrations found.

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

Summary

ID

NL-OMON23874

Source
Nationaal Trial Register

Brief title
Enbrel i.a.

Health condition

Rheumatoid arthritis
Psoriatic arthritis
Ankylosing spondylitis

Reumatoide artritis
Artritis psoriatica
Ziekte van Bechterew

Sponsors and support

Primary sponsor: Prof. dr. P.P. Tak, internist-reumatoloog
Afd. Klinische immunologie en reumatologie
F4-218
Meibergdreef 9
1105 AZ Amsterdam
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Source(s) of monetary or material Support: self-financing (sponsor)

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in clinical symptoms of inflammatory arthritis between placebo and intervention group.

Secondary outcome

The secondary endpoints of this study are (measured at all time points):
- Safety endpoints
- Acute phase reactants: Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP)
- several questionnaires

Study description

Study objective

Intra-articular etanercept therapy reduces the clinical signs and symptoms of inflammatory arthritis and improves outcome.

Study design

0, week 1, week 2, week 3, week 4 and week 6

Intervention

- one intra-articular injection with 25 mg etanercept or placebo (0.9% NaCl), follow up of 6 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Provision of a written informed consent

2. Age range 18-85

3. Presence of active knee arthritis

4. Presence of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis

(- Patients with RA for at least 6 months, diagnosed according to the revised 1987 ACR criteria for the classification of RA; Patients with AS for at least 6 months, diagnosed according to the ACR criteria for Spondylarthropathy; Patients with AS or PsA for at least 6 months, diagnosed according to CASPAR criteria)

Exclusion criteria

1. Contra-indication for TNF-blockade

2. Contra-indication for intra-articular treatment

3. Bone/ joint surgery within 8 weeks prior to inclusion, or joint surgery planned within 24 weeks of inclusion.

4. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study and/or evidence of an uncooperative attitude.

5. Clinical judgment by the investigator that the subject should not participate in the study, such as severe co-morbidity
Exclusions are in line with warning and contra-indications in the SmpC.

6. Use of DMARDs other than methotrexate (MTX) within four weeks prior to inclusion.

7. Patients or reproductive potential (males and females) must use a reliable means of contraception (e.g. contraceptive pill, IUD, physical barrier).

8. Intra-articular or parenteral corticosteroids within 3 months prior to inclusion.

9. Oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily within 4 weeks prior to inclusion.

10. Receipt of a live vaccine within 4 weeks prior to randomization.

11. Previous treatment with etanercept (Enbrel) or any other form of systemic anti-TNFa therapy.

12. Known active bacterial, viral, fungal, mycobacterial or other infection (including tuberculosis, or atypical mycobacterial disease, but excluding fungal infections of nail beds), or any major episode of infection requiring hospitalization or treatment with IV antibiotics within 4 weeks of screening or oral antibiotics within 2 weeks prior to screening. Patients with a positive PPD skin test should take isoniazide for at least 4 weeks before they can be included in the study.

13. History of recurrent significant infection or history of recurrent bacterial infections.

14. Primary or secondary immunodeficiency (history of, or currently active).

15. Pregnant women or nursing (breastfeeding) mothers.

16. History of cancer, including solid tumors and hematologic malignancies (except basal cell or squamous cell carcinoma of the skin that have been excised and cured).

17. Sever heart, kidney, and/or lung disease

18. Creatinine > 175 umol/l

19. Leucopaenia < 3.5 x 10e9/l

20. Thrombocytopaenia <125 x10e9/l

21. Haemoglobin <8.5 g/dl

22. AST or ALT > 2.5 times upper limit of normal

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2008
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	30-01-2008
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	NL1165
NTR-old	NTR1210
Other	MEC Academic Medical Center, Amsterdam, departement of clinical immunology and rheumatology : 07/298
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A