Exploratory trial on intra-articular etanercept treatment in inflammatory arthritis

Published: 03-03-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON35697

Source
ToetsingOnline

Brief title
Enbrel i.a

Condition

- Autoimmune disorders
- Joint disorders

Synonym
chronic joint inflammation, Inflammatory arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: etanercept treatment, inflammatory arthritis, intra-articular

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in clinical symptoms of inflammatory arthritis between placebo and intervention group. Success of treatment will be defined by the composite change index (CCI) at multiple time points (week 0-6).

Separate variables of the composite change index include:

- 100 mm visual analogue scale: VAS subject*s assessment of pain
- Evaluation of functional disability of the treated joint, joint swelling and joint tenderness (semi quantitative score, 0-3) by physician
- Patient*s and physician*s global assessment of the effect of therapy (semi quantitative score, 0-3)

Secondary outcome

The secondary endpoints of this study are:

- Safety endpoints
- Acute phase reactants: Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP)
- Immunogenicity parameters: serum etanercept levels, antibodies to etanercept
- 100 mm visual analogue scale: VAS subject*s assessment of disease activity and VAS physician's global assessment of patient's current disease activity
- Joint assessments: DAS28, DAS68, Ritchie Articular Index

- Questionnaires: HAQ, SF-36, BASDAI

Study description

Background summary

TNF blockade is an effective therapeutic approach in rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. There is still an unmet need for optimal local, intra-articular treatment in patients with monoarthritis or oligoarthritis caused by this disease. Moreover, not all patients respond to intra-articular corticosteroids or tolerate (intra-articular) corticosteroids. Little is known about the effects of local treatment with etanercept, and although initial studies have suggested safety of this approach, this has not been tested in a randomized placebo-controlled setting.

Study objective

The primary objective is to determine if intra-articular etanercept therapy reduces the clinical signs and symptoms of inflammatory arthritis and improve outcome (beneficial effect). The secondary objective is to study safety and to analyse immunogenicity parameters.

Study design

Monocenter, double-blind, randomized, placebo-controlled study with a follow-up time of 6 weeks.

Intervention

One intra-articular injection of 25 mg etanercept (Enbrel®) or matching placebo (NaCl 0.9%).

Study burden and risks

During this study patients are exposed to the risks associated with the use of etanercept, injection site reactions being the most common reported adverse event. Complications of the procedure (intra-articular injection) are very rare and consist of infection of wound or the joint.
Patients are required to visit the hospital 7 times. During each visit the patient will be asked to fill out questionnaires, blood will be taken and a physical examination will be done.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Provision of a written informed consent
2.Age range 18-85
3.Presence of active knee, ankle, wrist, elbow or MCP arthritis
4.Presence of rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis
-Patients with RA for at least 3 months, diagnosed according to the revised 1987 ACR criteria for the classification of RA
-Patients with AS or PsA for at least 3 months, diagnosed according to the modified New York criteria and CASPAR criteria respectively

Exclusion criteria

- Contra-indication for TNF-blockade or intra-articular treatment
- Bone or joint surgery 8 weeks prior to inclusion
- Arthroscopy within 2 weeks prior to inclusion, or arthroscopy planned during the time of the study
- Intra-articular or parenteral corticosteroids within 3 months prior to inclusion.
- Oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily within 4 weeks prior to inclusion.
- Use of DMARDs other than methotrexate (MTX) within 4 weeks prior to inclusion.
- Receipt of a live vaccine within 4 weeks prior to randomization.
- Treatment with Etanercept (Enbrel) or any other form of systemic anti-TNFa therapy within 3 months prior to inclusion
- 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.
- History of recurrent significant infection or history of recurrent bacterial infections.
- Primary or secondary immunodeficiency (history of, or currently active).
- Pregnant women or nursing (breastfeeding) mothers.
- History of cancer in the past 10 years, including solid tumors and hematologic malignancies (except basal cell or squamous cell carcinoma of the skin that have been excised and cured) or a history of cancer more than 10 years ago without curative treatment
- Sever heart, kidney, and/or lung disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Etanercept
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	13-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2007-006118-40-NL

Register	ID
CCMO	NL20331.018.07