Dose-to-target of etanercept treatment in rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24861

Source
Nationaal Trial Register

Health condition

Etanercept, dose-to-target, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, personalized medicine

Sponsors and support

Primary sponsor: Jan van Breemen Research Institute | Reade
Source(s) of monetary or material Support: Jan van Breemen Research Institute | Reade

Intervention

Outcome measures

Primary outcome

To determine the proportion of patients with RA, AS or PsA maintaining Minimal Disease Activity after dose interval prolongation of etanercept.

Secondary outcome

1. To study the cost-effectiveness of tapering down etanercept treatment;

2. To investigate whether the lowest effective etanercept dose will reduce the risk of adverse events;

3. To study the predictive value of serum etanercept trough levels and other patient related factors for successful down titration.

Study description

Background summary

Objective:

To determine the proportion of patients with RA, AS or PsA maintaining minimal disease activity (MDA) after dose interval prolongation of etanercept.

Secondary objectives: To study the cost-effectiveness of tapering down etanercept treatment, to investigate whether the lowest effective etanercept dose will reduce the risk of adverse events and to study the predictive value of serum etanercept trough levels for successful down titration.

Study design:

Open randomized controlled study of a dose-to-target step-down treatment strategy of etanercept which consists of 2 phases, including 150 rheumatoid arthritis, 50 psoriatic arthritis and 50 ankylosing spondylitis patients.

Intervention:

Patients with Minimal Disease Activity who are treated with etanercept for at least 6 months will be randomly assigned to continuation of etanercept every week or prolongation of the dosage interval to once every 2 weeks (phase 1). Patients will be followed for 6 months. Thereafter, the second phase of this study starts, in which patients, who are still in a state of minimal disease activity, will be further down-titrated to either etanercept 50 mg every two weeks (continuation group first phase) or discontinuation of etanercept. Patients will be followed for an additional 6 months.

Main study parameters:

Minimal Disease Activity define whether a patient is suitable for inclusion and randomisation. Definition of Minimal Disease Activity is specified for every disease separately. Etanercept serum concentrations, disease activity and cost related parameters will be measured during follow-up.

Study objective

A proportion of patients with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis with minimal disease activity can remain in a state of minimal disease activity with a lower dose of etanercept (50 mg every two weeks instead of every week) or even without etanercept.

Study design

After inclusion at baseline patients will be monitored every 3 months during the first (6 months duration) and second (6 months duration) phase of the study.

Intervention

Phase 1:

Patients with low disease activity will be randomly assigned to continuation of etanercept 50 mg per week or etanercept 50 mg per two weeks. Patietns will be followed for 6 months.

Phase 2:

Patientens who remained in a state of low disease activity with etanercept 50 mg per two weeks will stop with etanercept. Patients who were still on standard treatment and who are in a state of low disease activity will continue with etanerceot 50 mg per two weeks. Patients will be followed for 6 months.

Contacts

Public
Dr. Jan van Breemenstraat 2, 1065 AB Amsterdam
G.J. Wolbink
Amsterdam 1056 AB
The Netherlands
020-5896 589
Scientific

Dr. Jan van Breemenstraat 2, 1065 AB Amsterdam
G.J. Wolbink
Amsterdam 1056 AB
The Netherlands
020-5896 589

Eligibility criteria

Inclusion criteria

1. Diagnosis: RA (according to the American College of Rheumatology 1987 criteria), or PsA (according to the Classification of Psoriatic Arthritis criteria) or AS (according to the 1984 New York Criteria);

2. Treatment with etanercept 50 mg SC weekly (or 25 mg SC twice weekly) for at least 6 subsequent months;

3. Minimal Disease Activity: Outcome Measures in Rheumatology (OMERACT) MDA criteria for RA, MDA criteria for PsA which are defined in collaboration with the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and Ankylosing Spondylitis Disease Activity Score (ASDAS), using C-reactive protein (CRP), inactive or moderate disease activity;

4. Written informed consent.

Exclusion criteria

Planned reasons for treatment discontinuation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-03-2013
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	NL3705
NTR-old	NTR3903
Other	ABR nummer CCMO : 43897
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A