Dose-to-target of etanercept treatment: a dose-tapering randomized controlled trial in patients with rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis.

Published: 27-05-2013
Last updated: 24-04-2024

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...

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

Summary

ID

NL-OMON38584

Source
ToetsingOnline

Brief title
Dose-to-target of etanercept treatment in rheumatic diseases.

Condition

- Autoimmune disorders

Synonym
ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Eigen financiering via Reade

Intervention

Keyword: dose-to-target, Etanercept, personalized medicine, rheumatic diseases

Outcome measures

Primary outcome

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.

Secondary outcome

cost-effectiveness

the risk of adverse events.

etanercept trough levels

Study description

Background summary

The proportion of patients with rheumatic diseases treated with biologics has increased considerably over the last decade. As a consequence, the financial burden for the health care system has increased enormously. Therefore, dose reduction of biologics is currently a hot topic in rheumatology practice. However, there is limited information about the success rate of dose tapering or discontinuation as well as predictors of success and the risks of dose reduction, like deterioration of disease activity and radiographic progression. Recently, a few studies in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) patients on biologics were published but these

studies have some major limitations: limited numbers of patients, different criteria for inclusion and remission and flare were used, in some only retrospective data was available.

Study 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 12 months.

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 standaard treatment and who are in a state of low disease activity will continue with etanerceot 50 mg per two weeks. Patientes will be followed for 12 months.

Study burden and risks

Nature and extent of the burden: We hypothesize that patients with Minimal Disease Activity will remain in a state of Minimal Disease Activity after dose interval prolongation of etanercept, however, an increased disease activity risk can not be excluded, especially in patients discontinuing etanercept.

Contacts

Public
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL
Scientific
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis: Rheumatoid Arthritis (according to the American College of Rheumatology 1987 criteria), or Psoriatic Arthritis (according to the Classification of Psoriatic Arthritis criteria) or Ankylosing spondylitis (according to the 1984 New York Criteria).
Treatment with etanercept 50 mg subcutaneously (SC) weekly (or 25 mg SC twice weekly) for at least 6 subsequent months.
Minimal Disease Activity (MDA): 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.
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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2013
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
CCMO	NL43897.048.13