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

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24861

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Jan van Breemen Research Institute | Reade
Overige ondersteuning: Jan van Breemen Research Institute | Reade

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Planned reasons for treatment discontinuation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3705
NTR-old	NTR3903
Ander register	ABR nummer CCMO : 43897
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A