Dose-to-target of etanercept treatment in patients with juvenile idiopathic arthritis in patients age 12 years and older.

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A proportion of patients with juvenile idiopathic arthritis with minimal disease activity can remain in a state of minimal disease activity with a lower dose of etanercept than the standard dose or even without etanercept.

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

Samenvatting

ID

NL-OMON20690

Bron
NTR

Aandoening

etanercept, juvenile idiopathic arthritis, dose tapering, discontinuation

Ondersteuning

Primaire sponsor: Jan van Breemen Instituut, Reade
Overige ondersteuning: Jan van Breemen Instituut, Reade and Achmea (zorgverzekeraar)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the proportion of patients with JIA maintaining Minimal Disease Activity after

dose interval prolongation of etanercept.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 juvenile idiopathic arthritis (JIA) on etanercept were published but these studies have some major limitations: limited numbers of patients with different subtypes of JIA were included and only retrospective data were available. In addition, to our knowledge no study has been performed in patients with JIA age 17 years or older.

Objective: To determine the proportion of patients with JIA 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: Prospective observational study a dose-to-target step-down treatment strategy of etanercept which consists of 2 phases, including all suitable JIA patients currently treated in our institute.

Intervention: Patients with Minimal Disease Activity at baseline and with clinically low disease activity for at least 6 months during etanercept treatment will be approached for participation. After inclusion, etanercept dose interval will be prolonged 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 discontinue etanercept. Patients will be followed for an additional 6 months.

Main study parameters: Minimal Disease Activity will define whether a patient is suitable for inclusion and randomisation. Definition of Minimal Disease Activity (MDA) is according to the

JADAS cut-off values for minimal disease activity. Patients should be in MDA at baseline and clinically in low disease activity according to the treating rheumatologist, for at least 6 months. Etanercept serum concentrations, disease activity, functional ability, quality of life and cost related parameters will be measured during follow-up.

Doel van het onderzoek

A proportion of patients with juvenile idiopathic arthritis with minimal disease activity can remain in a state of minimal disease activity with a lower dose of etanercept than the standard dose 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 or 0,8 mg/kg per week or etanercept 50 mg per two weeks or treatment with etanercept of 0,8 mg/kg per 2 weeks. Patients will be followed for 6 months.

Phase 2:

Patientens who remained in a state of low disease activity with etanercept 50 mg or 0,8 mg/kg 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 etanercept 50 mg or 0,8 mg/kg 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)

• Diagnosis: JIA, types: polyarthritis (RF negative and RF positive), oligo-arthritis (persistant and extended), psoriasic and enthesitis related arthritis and undifferentiated arthritis (according to the ILAR criteria).

• Age 12 years or older.

• Treatment with etanercept 50 mg SC weekly (or 25 mg SC twice weekly) or treatment with weekly dose etanercept of 0,8 mg/kg for at least 6 subsequent months.

• Minimal Disease Activity, according to the JADAS criteria for Minimal Disease Activity at baseline and clinically low disease activity according to the rheumatologist for at least 6 months to baseline.

• No uveitis for a minimum of 12 months.

• No use of systemic corticosteroids or intra-articular steroids for a minimum of 6 months prior to baseline.

• Written informed consent by the patient (and if applicable, the parents).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Planned reasons for treatment discontinuation.

• JIA, type: systemic arthritis.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-05-2014
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	NL4516
NTR-old	NTR4634
Ander register	METC : P1438

Resultaten

Samenvatting resultaten
N/A