

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

No registrations found.

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

Summary

ID

NL-OMON20690

Source

Nationaal Trial Register

Health condition

etanercept, juvenile idiopathic arthritis, dose tapering, discontinuation

Sponsors and support

Primary sponsor: Jan van Breemen Instituut, Reade

Source(s) of monetary or material Support: Jan van Breemen Instituut, Reade and Achmea (zorgverzekeraar)

Intervention

Outcome measures

Primary outcome

To determine the proportion of patients with JIA 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

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.

Study objective

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.

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 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:

Patients 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.

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosis: JIA, types: polyarthritis (RF negative and RF positive), oligo-arthritis (persistent and extended), psoriatic 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).

Exclusion criteria

- Planned reasons for treatment discontinuation.
- JIA, type: systemic arthritis.

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):	01-06-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion	
Date:	22-05-2014
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

NTR-new

NTR-old

Other

ID

NL4516

NTR4634

METC : P1438

Study results

Summary results

N/A