Dose-to-target of etanercept treatment: a dose-tapering randomized controlled trial in patients with juvenile idiopathic arthritis in patients age 12 years and older.

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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...

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

Summary

ID

NL-OMON40793

Source
ToetsingOnline

Brief title
Dose-to-target of etanercept in patients with JIA age >=12 years

Condition

- Autoimmune disorders

Synonym
juvenile idiopathic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Achmea (zorgverzekeraar)

Intervention

Keyword: dose-to-target, Etanercept, juvenile idiopathic arthritis, personalized medicine

Outcome measures

Primary outcome

To determine the proportion of patients with JIA maintaining Minimal Disease

Activity after dose interval prolongation of etanercept.

Secondary outcome

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.

To study the predictive value of serum etanercept trough levels and other

patient related factors for successful down titration.

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 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.

Study 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

Randomized controlled trial: 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. 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.

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. Thereafter, patients of the control arm in whom disease activity is low after 6 months of etanercept dose reduction, etanercept will also be discontinued.

Study burden and risks

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 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).

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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2014
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	NL49544.048.14
Other	NTR nummer is aangevraagd