A Multicenter, Double Blind, Randomized-Withdrawal Trial of Subcutaneous Golimumab, a Human Anti-TNF?? Antibody, in Pediatric Subjects with Active Polyarticular Course Juvenile Idiopathic Arthritis (JIA) Despite Methotrexate Therapy

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

Summary

ID

NL-OMON36723

Source
ToetsingOnline

Brief title
Go-Kids

Condition

- Autoimmune disorders

Synonym
artritis, JIA

Research involving
Human

Sponsors and support

Primary sponsor: Centocor Netherlands B.V.
Source(s) of monetary or material Support: Centocor

Intervention

Keyword: JIA, Juvenile Arthritis

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects who are ACR Ped 30

responders (as defined in Section 9.2.1.3) at Week 16 and do not experience a

flare of disease between Week 16 and Week 48.

Secondary outcome

1. The proportion of ACR Ped 30 responders at Week 16 with ACR Ped 30 response

at Week 48.

2. The proportion of subjects who are responders at Week 16 and have inactive

disease at Week 48.

3. The proportion of subjects, who are responders at Week 16 and are in

clinical remission (as defined in Section 9.2.1.3) while on medication for JIA

at Week 48.

Study description

Background summary

JIA is the most common chronic rheumatic disease in children and an important cause of short-term and long-term disability in children.

Although the etiology and pathogenesis of JIA are still unclear, the same cell types and underlying mechanisms that play a role in the progression of adult RA are probably involved.
Some studies have shown that levels of inflammatory cytokines (eg, interleukin-1 beta [IL 1**, interleukin-6 [IL-6], and TNF*) elevated in adults with RA are also elevated in the synovial fluid and serum of patients with JIA.
While there are no current data on the use of golimumab in the pediatric population, there are abundant, relevant data available on the use of golimumab in the adult population with rheumatic diseases, and on the use of other anti-TNF agents such as infliximab, entanercept, and adalimumab in both the adult and pediatric populations with rheumatic diseases.
In studies of golimumab in adult rheumatologic diseases, the types of adverse events reported have been similar to those reported with established anti-TNF* agents.

Study objective

The primary objective of this study is to assess the clinical efficacy of SC administration of golimumab in pediatric subjects (ages 2 to less than 18 years) with JIA manifested by more or equal to 5 joints with active arthritis despite MTX therapy for more or equal to 3 months (Section 9.2.1.3).

Study design

This is a randomized withdrawal, double-blind, placebo-controlled, parallel-group, multicenter study of SC golimumab in pediatric subjects with active JIA despite current treatment with MTX. At least 170 subjects will be enrolled at Week 0 to ensure that at least 134 subjects are randomized into the randomized withdrawal portion of the study.
All subjects will receive golimumab untill Week 12. Those who respond well, will be enrolled to receive the study medication, which is 50/50 golimumab/placebo through to week 48 of the study.

If the subject has a measured arthritic flare up between weeks 16 and 48, the study doctor can find out which medication was received, and if it was placebo he/she will be put back on golimumab for the rest of the study.

At week 48, the sponsor will find out which medication was given and if placebo was given and no improvement the subject will be switched to golumimab.

When the study is unblinded after all subjects have finished Week 48, the subjects will be getting golimumab until week 144, which is the end of the treatment period, except when the a subject has responded well on placebo; then the study will end for this subject.
The child will continue taking MTX as he/she currently takes, along with folic acid therapy at the dose he/she was on at the start of the study. If the child

has been on a stable dose of corticosteroids or anti-inflammatory medications, he/she will most likely be able to stay on these during the entire study.

Intervention

The study will have 1 active treatment group. The test products, golimumab and placebo, will be prepared by a blinded pharmacist from a prefilled syringe (PFS) and transferred to a graduated syringe under sterile conditions.
Subjects will receive 30 mg/m2 golimumab SC injection to a maximum dose of 50 mg. Subjects will also receive commercial MTX weekly at their fixed dose at time of study entry and commercial folic acid ** 5 mg weekly or folinic acid (at half the MTX dose) given the day after the MTX dose.

Study burden and risks

Golimumab has recently been demonstrated to be efficacious in adults with RA, PsA, and AS. Other anti-TNF agents have been effective in the treatment of pediatric subjects with juvenile idiopathic arthritis.
Allthough it is expected that the subject will benefit from this studymedication, he/she will still receive the standard treatment as background therapy.
The set-up and procedures of this study will not put a major burden on the subject, except for the long duration and frequent visits to the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Pediatric subject ages 2 to less than 18 years of age.
* Diagnosis must be made per JIA ILAR diagnostic criteria and the onset of disease must have been before the subject*s 16th birthday
* Disease duration of at least 6 months before study entry.
* May have been previously treated with no more than 1 therapeutic agent targeted at reducing TNF*.

Exclusion criteria

** Have known allergies, hypersensitivity, or intolerance to golimumab or other immunoglobulins or its excipients
* Are pregnant or breast-feeding, or planning a pregnancy or fathering a child within 6 months after the last study agent administration.
* Have a past history of macrophage activation syndrome (MAS).
* Have received an investigational drug (including vaccines) or used an investigational medical device recently
* Have initiated DMARDS and/or immunosuppressive therapy within 4 weeks prior to study initiation.
* Have other inflammatory disease that might confound the evaluation of benefit from golimumab therapy
* Have current side effects related to MTX which would preclude treatment with MTX
* Have a history of or ongoing chronic or recurrent infectious disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2011
Enrollment:	7
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Golimumab
Generic name:	SIMPONI
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-10-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-12-2010

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2013

Application type:	Amendment
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
Other	0
EudraCT	EUCTR2009-015019-42-NL
CCMO	NL33704.018.10