A Phase 1b Open-Label Study to Assess the Safety and Pharmacokinetics of Subcutaneously Administered Golimumab, a Human anti-TNFα Antibody, in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON40329

Source
ToetsingOnline

Brief title
PURSUIT PEDS PK

Condition

- Gastrointestinal inflammatory conditions

Synonym
idiopathic chronic inflammatory disease

Research involving
Human

Sponsors and support

Primary sponsor: Janssen Biologics B.V.
Source(s) of monetary or material Support: the pharmaceutical industry

Intervention

Keyword: Active Ulcerative Colitis, human anti-TNFalpha antobody, pharmacokinetics, safety

Outcome measures

Primary outcome

The primary outcome of this study is to assess PK (eg, serum golimumab concentration at Week 6 and area under the curve from 0 to 6 weeks [AUC0-6 weeks]).

Secondary outcome

Major secondary outcomes include safety through Week 6 and Week 126, as well as clinical response, clinical remission, and mucosal healing, all at Week 6, and Pediatric Ulcerative Colitis Activity Index (PUCAI) remission at Week 54 and Week 110.

Study description

Background summary

Golimumab is a fully human monoclonal antibody with an IgG1 heavy chain isotype (G1m[z] allotype) and a kappa light chain isotype. Golimumab binds to human tumor necrosis factor alpha (TNFα) with high affinity and specificity and neutralizes TNFα bioactivity.
Golimumab has been shown to be safe and efficacious in adults with moderately to severely active ulcerative colitis (UC). Golimumab has the potential to offer pediatric patients with moderately to severely active UC a safe and effective therapy with a convenient subcutaneous (SC) injection option given

every 4 weeks (q4w).

Study objective

The primary study objectives are as follows:
-To evaluate the pharmacokinetics (PK) of golimumab in pediatric subjects aged 2 through 17 years with moderately to severely active UC.
-To evaluate the safety of golimumab in pediatric subjects aged 2 through 17 years with moderately to severely active UC.
An additional objective is to evaluate the efficacy of golimumab induction (ie, short-term therapy) in pediatric subjects aged 2 through 17 years with moderately to severely active UC.

Study design

This is a multicenter, open-label study to assess the PK and safety of golimumab treatment in pediatric subjects aged 2 through 17 years with moderately to severely active UC, defined as a baseline Mayo score of 6 through 12, inclusive, with an endoscopy subscore of >= 2. The study will be divided into 2 parts: the PK portion of the study and the study extension.
-PK portion: Subjects will receive induction dose regimens of SC golimumab at Week 0 and Week 2 based on body weight. At Week 6, all subjects will be evaluated for clinical response; subjects in clinical response will continue to receive open label golimumab maintenance therapy and will have the opportunity to participate in the study extension that begins at Week 14. Subjects not in clinical response at Week 6 will be withdrawn from further study agent administration.
-Study Extension: Subjects in clinical response at Week 6 will continue to receive open label golimumab maintenance therapy and will enter the study extension at Week 14. During the study extension, subjects will receive golimumab maintenance therapy every 4 weeks (q4w) through Week 110.
-At Week 114, subjects who, in the opinion of the investigator, may benefit from continued treatment will be eligible to continue to receive golimumab q4w under this protocol until marketing authorization is obtained for golimumab in the treatment of pediatric UC in that country, or until a decision has been made not to pursue an indication in pediatric UC, whichever occurs first.
An internal Safety Monitoring Committee, consisting of a clinician and a statistician at a minimum, will monitor the safety data of the subjects in this study on an ongoing basis.

Intervention

The study will be divided into 2 parts: the PK portion of the study and the study extension.
-PK portion: Subjects will receive induction dose regimens of SC golimumab at Week 0 and Week 2.

-Study Extension: Subjects in clinical response at Week 6 will continue to receive open label golimumab maintenance therapy and will enter the study extension at Week 14. During the study extension, subjects will receive golimumab maintenance therapy every 4 weeks (q4w) through Week 110.
At Week 114, subjects who, in the opinion of the investigator, may benefit from continued treatment will be eligible to continue to receive golimumab q4w under this protocol.

Study burden and risks

Possible burden of the patient, related to the testing of the study will be tests, will be such as Sigmoidoscopy, but this could also be standard procedure of testing for patients with ulcerative colitis. Sigmoidoscopy and tests such as the tuberculosis test can be experienced as unpleasant.
Further burden will be blood sampling and the visit days throughout the study, during which childeren will be accompanied by their parents/guardians.

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

• Moderate to severe Ulcerative Colitis (UC) defined by a Mayo score (a score used to assess the treatment for UC) of 6 to 12 inclusive, including an endoscopic subscore of 2 or more.
• Must either be currently receiving treatment with, or have a history of having failed to respond to, or have a medical contraindication to at least 1 of the following therapies: oral or intravenous corticosteroids, 6-mercaptopurine and azathioprine OR
• must either have or have had a history of corticosteroid dependency (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC) OR
• required more than 3 courses of corticosteroids in the past year
• No history of latent or active tuberculosis prior to screening
• Positive protective antibody titers to varicella and measles prior to the first administration of study agent

Exclusion criteria

• Have severe extensive UC that is likely to require a colectomy (surgical removal of the colon) within 12 weeks of study entry
• Have UC limited to the rectum only or to less than 20 cm of the colon
• Presence of a stoma
• Presence or history of a fistula
• Have evidence of Crohn's disease (an inflammatory large intestine disease)
• Previous exposure to anti-tumor necrosis factor therapy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2013
Enrollment:	4
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	16-08-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-10-2014

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2012-004366-18-NL
ClinicalTrials.gov	NCT01900574
CCMO	NL44458.078.13