Study of the pharmacokinetics of golimumab in moderate to severe Ulcerative Colitis

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To gain insights in the pharmacokinetics of golimumab in moderate to severe Ulcerative Colitis after subcutaneous administration, during induction and maintenance treatment.

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

Summary

ID

NL-OMON44551

Source
ToetsingOnline

Brief title
GO-KINETIC

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease, Ulcerative Colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Drug levels, Golimumab, Pharmacokinetics, Ulcerative Colitis

Outcome measures

Primary outcome

Drug level of golimumab at several time points.

Secondary outcome

Development of anti-drug antibodies, fecal calprotectin, fecal golimumab drug levels, serum CRP, albumin level, SCCAI, IBDQ, SF-36 and endoscopies at different time points.

Study description

Background summary

Golimumab was recently registered for moderate to severe ulcerative colitis in patients failing conventional treatment (5-aminosalicylates, corticosteroids and/or immunomodulators, such as azathioprine and 6-mercaptopurine) or are intolerant for such therapies. The efficacy and safety has been demonstrated in clinical trials, but experience in daily clinical practice is lacking. Although golimumab is a new treatment option for patients with moderate to severe ulcerative colitis, there are still many patients who do not respond or have loss of response to golimumab. Importantly, clinical efficacy during induction and maintenance therapy seems to correlate with golimumab trough levels. Patients in the higher serum concentration quartiles had more favourable outcomes versus patients in the lower quartiles. This exposure * effect relationship needs further research in order to determine the optimal therapeutic window and possible clinical benefit of therapeutic drug monitoring. Therefore, we aim to provide pharmacokinetic data of induction and maintenance treatment in UC patients who will start with golimumab. Clinical efficacy will be correlated with golimumab exposure (AUC, trough levels). Moreover, we will try to determine the optimal therapeutic window for golimumab serum levels. The hypothesis is that a suboptimal effect of golimumab in moderate - severely active UC patients may be due to subtherapeutic serum levels due to consumption of the antibody in the mucosal bowel compartment.

Study objective

To gain insights in the pharmacokinetics of golimumab in moderate to severe Ulcerative Colitis after subcutaneous administration, during induction and maintenance treatment.

Study design

Prospective multicenter observational study.

Study burden and risks

Patients will undergo 16 blood (15 cc) sample collections, 16 stool sample collections and 3 endoscopies during 16 hospital visits in 1 year. They are also asked to fill in a short questionnaire (9x). At endoscopy visits a questionnaire regarding quality of life will be taken. Risks involved in endoscopies are perforation or bleeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age from 18 years, either male or female
-Moderate to severe Ulcerative Colitis (according to Mayo score (2 or 3) baseline Colonoscopy), both anti-TNF naïve and anti-TNF exposed patients will be included
-Baseline endoscopy
-Obtained written informed consent

Exclusion criteria

- Contra-indication to golimumab: TBC, severe infections or congestive heart failure.
- Imminent need for surgery

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):	02-09-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2014

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	NL48785.018.14

Study results

Date completed:	31-12-2017
Actual enrolment:	20