Study of the pharmacokinetics of Infliximab (IFX) in moderate to severe Ulcerative Colitis

Published: 04-05-2012
Last updated: 26-04-2024

To get a better understanding of the pharmacokinetics of IFX in Ulcerative Colitis, especially with regards to the circulating drug levels in the first 42 days after the start of therapy, and in relationship to the *inflammatory burden* by…

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

Summary

ID

NL-OMON37516

Source
ToetsingOnline

Brief title
KINETIC
druglevel Infliximab

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 level, Infliximab, Pharmacokinetics, Ulcerative Colitis

Outcome measures

Primary outcome

Drug level of Infliximab at several time points

Secondary outcome

Development of antibodies, fecal calprotectin en serum CRP, Albumine level,

Simple Clinical Colitis Activity Index, colonoscopy and biopsies at the

different time points

Study description

Background summary

Infliximab (IFX) has become a common treatment for Ulcerative Colitis (UC) and the first choice in patients with steroid-refractory disease. Among patients who initially respond to infliximab up to 40% will subsequently lose response. The development of antibodies to infliximab has been associated, in several studies, with decreased drug concentrations and a decreased clinical response. However, drug consumption due to massive presence of inflammation and mucosal TNF may represent another mechanism of early suboptimal response.
One Canadian study showed that patients with detectable trough level of infliximab not only have a higher rate of clinical remission, but also a lower serum CRP and a higher rate of endoscopic healing.
We hypothesize that a suboptimal effect of infliximab in UC patients could be related to subtherapeutic serum levels due to consumption of the antibody in the mucosal bowel compartment. In patients with acute severe bowel inflammation the circulating IFX level might therefore be lower.

Study objective

To get a better understanding of the pharmacokinetics of IFX in Ulcerative Colitis, especially with regards to the circulating drug levels in the first 42 days after the start of therapy, and in relationship to the *inflammatory burden* by Ulcerative Colitis.

Study design

Prospective observational multicenter study

Study burden and risks

Subjects will undergo several blood (15cc) and stool sample collections (outpatient:11, hospitalized:14), 2 colonoscopies, 6 physical examinations and questionnaires (SCCAI) will be taken in 11-14 distinct hospital visits.
Risks involved with colonoscopy and biopsies are perforation or bleeding.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

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) naïve to biologic therapy.
-Baseline Colonoscopy
-Obtained written informed consent

Exclusion criteria

-History of anti-TNF treatment
-Contra-indication to infliximab: TBC, severe infections or congestive heart failure.
-Imminent need for surgery
-Immunomodulators started in the last 4 weeks

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):	09-07-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2012
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	NL39626.018.12

Study results

Date completed: 03-04-2014

Actual enrolment: 20