Predicting trough levels in patients receiving infliximab maintenance therapy using interval (non-trough) serum infliximab levels

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Aim of this prospective study is to investigate the relation between non-trough serum IFX levels (4 and 6 weeks after infusion) and IFX trough levels (8 weeks after infusion) in patients with Crohn*s disease

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

Summary

ID

NL-OMON41068

Source
ToetsingOnline

Brief title
PREDIX

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, enteritis regionalis

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, Trough level

Outcome measures

Primary outcome

Serum infliximab level at week 0, 4, 6 and 8.

Secondary outcome

CRP, albumin

Study description

Background summary

Infliximab (IFX) is effective in inducing and maintaining remission in adults and children with Crohn*s disease (CD). Studies have shown the value of therapeutic drug monitoring (TDM) in the treatment of CD with IFX. TDM comprises the measurement of serum IFX levels and antibodies to infliximab (ATI), and adjusting treatment accordingly. Current TDM algorithms are exclusively based on IFX trough levels (i.e. the lowest IFX concentration immediately prior to the next dose). Since a rapid test for the determination of IFX levels is not available, the outcome of TL measurements is only available after the next IFX dose has already been administered. Therefore, it would be of great value if physicians can be informed of whether a patient*s current IFX dosage is adequate at other time points than only immediately prior to IFX administration.

Study objective

Aim of this prospective study is to investigate the relation between non-trough serum IFX levels (4 and 6 weeks after infusion) and IFX trough levels (8 weeks after infusion) in patients with Crohn*s disease

Study design

Prospective observational study

Study burden and risks

Participation will result in additional blood sampling and two additional venous punctures at week 4 and 6 (for blood sampling at week 0 and 8, no additional venous puncture is required since patients will already receive intravenous cannulation for IFX administration).

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 *18 years
- Crohn*s disease based on endoscopy and pathology
- Clinical remission based on a Harvey Bradshaw Index score of <5

- Biochemical remission based on fecal calprotectin levels of <250µg/g
- Scheduled IFX maintenance therapy with 5mg/kg body weight every 8 weeks

Exclusion criteria

- Change in immunomodulator co-treatment within the previous 3 months
- Previous non-adherence to the 8-week infusion schedule

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):	22-07-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2014
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	NL49550.018.14