Evaluating a rapid on-site test for the monitoring of infliximab trough levels- a pilot study

Published: 13-05-2015
Last updated: 16-04-2024

To determine the correlation between concetrations of inflextra/ infliximab as measured using finger prick blood and lateral-flow assay and using venous blood and the standard sanquin ELISA.

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

Summary

ID

NL-OMON43725

Source
ToetsingOnline

Brief title
Evaluation of a rapid lateral-flow assay for infliximab

Condition

- Gastrointestinal inflammatory conditions

Synonym
crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biological, inflammatory bowel disease, infliximab, Therapeutic drug monitoring

Outcome measures

Primary outcome

correlation between the infliximab/ inflectraTL determined by the lateral flow

assay TL and the traditional ELISA

Secondary outcome

The accuracy of quantitative measurements in the IFX concentration range of

2-12 mg/mL, to determine how results potentially can be used to immediately

change infusion schemes

The duration of the test, measured from taking the blood samples to receiving

the result.

Study description

Background summary

Anti-TNF antibodies are considered to be potent treatment modality for inflammatory bowel disease patients (Terdiman et al., 2013). Infliximab was the first anti-TNF available for the treatment of IBD patients and has been reported to be efficacious for both the induction as the maintenance of remission in patients with Crohn*s disease as well as patient with ulcerative colitis (Terdiman et al., 2013).
Up to 50% of patients will develop loss of response to infliximab (Ben-Horin et al., 2014). In a given patient, a number of strategies exist to try and overcome this loss of response such as escalation of the dose or switching to another anti-TNF drug. However, the preferred route is via measuring of trough levels and antibodies to infliximab as this enables to identify patients that may benefit from dose escalation and patients who fail in spite of having therapeutic drug trough levels (Ben-Horin et al., 2014).
Studies on therapeutic drug monitoring, which encompasses measurement of infliximab through levels (TL) and measurement of antibodies to infliximab (ATI), have shown that patients in remission may have widely differing TLs.

Patients with a low TL may benefit from optimizing dosage in order to prolong the remission period. In patients with a supra-therapeutic TL may reduce the change for side effects when the dose is reduced (or the interval between visits increased). An additional benefit in this scenario would be that, as infliximab is an expensive drug, reducing the dose might yield important savings.
However, currently infliximab TL measurements are beholden to specialized laboratories and the sending and processing of blood samples precludes on site measurement of TLs. When it would be feasible to measure the TL just before the infusion starts, it may be possible to reduce (or increase) the planned amount of infliximab.
Recently, our group has performed a proof of principle study (Corstjens et al., 2013) on a rapid lateral flow-based assay format that could enable on-site monitoring of infliximab TLs. In that study, an excellent correlation was observed between the results of the lateral flow-assay and the standard ELISA infliximab assay. However, blood was taken by venapunction and measurements were performed in serum. Furthermore, the current lateral flow reader uses phosphorus as this enables measurement of lower concentrations. However, the use of a gold-based reader would enable a more rapid analysis and, as these readers are available of the shelve, would reduce assay costs.

Study objective

To determine the correlation between concetrations of inflextra/ infliximab as measured using finger prick blood and lateral-flow assay and using venous blood and the standard sanquin ELISA.

Study design

prospective multicentre observational pilot study

Study burden and risks

minor risk, as the only extra action is a fingerprick

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

• Diagnosis of ulcerative colitis, Crohn*s colitis or IBD unclassified
• Current use of infliximab
• Age > 18 years
• Signed informed consent

Exclusion criteria

Refusal to participate

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-04-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL52468.058.15