Lateral Flow Assay for Detection of Through Tumor Necrosis Factor Alpha (Infliximab) levels

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Monitoring of serum drug levels may help to optimize dosing schedules and decrease the risk of infusion reactions and subsequent treatment failure. In the future we want to routinely measure anti-TNF levels in IBD patients that are treated with...

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

Summary

ID

NL-OMON32551

Source
ToetsingOnline

Brief title
Lateral flow assay for TNF detection

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lateral flow assay, Through levels, Tumor Necrosis Factor Alpha

Outcome measures

Primary outcome

To test the feasibillity of lateral flw assay for measuring infliximab drug

levels

Secondary outcome

Not appropiate

Study description

Background summary

The chimeric monoclonal antibody to tumor necrosis factor (TNF-α), infliximab, is effective as an induction and maintenance therapy for patients with moderate-to-severe Crohn*s disease including fistula closure. However, it*s use is associated with the formation of antibodies to infliximab (ATIs) in 60% of the patients, which may lead to infusion reactions, loss of efficacy and delayed hypersensitivity reactions. The formation of infliximab-anti-infliximab complexes leads to fast clearance of infliximab and lower serum infliximab levels. This immunogenicity has important consequences for treatment outcome, since lower drug levels are associated with shorter duration of response after infusion9. In short, a good clinical response to treatment with infliximabi correlates with the presence of high serum trough infliximab levels and the absence of anti-infliximab antibodies, and inefficacy with the reverse. There are several strategies that may prevent or overcome a loss of response. It has been shown that ATI formation is less frequent when the drug is given as scheduled maintenance therapy. Also, concomitant immunosuppressive therapy (azathioprine or methotrexate) reduces immunogenicity and is associated with a longer duration of response.

Study objective

Monitoring of serum drug levels may help to optimize dosing schedules and decrease the risk of infusion reactions and subsequent treatment failure. In the future we want to routinely measure anti-TNF levels in IBD patients that are treated with infliximab and correlate prospectively drug levels with

clinical and laboratory parameters (C-reactive protein and calprotectin). This way we expect to gain insight whether and how drug level monitoring can predict response to therapy and the development of adverse effects. The results could be implicated in a therapeutic drug-monitoring-guided-therapy-strategy that may have a safety and efficacy advantage for the individual patient. However, in the current project we want to test lateral flow (LF)strips (see below) for measuring serum levels of infliximab. Results will be compared to standard laboratory testing by enzyme linked immunosorbent assay (ELISA). The ultimate aim of this feasibility study is to develop a *lab on chip* analysis that can be used in the future for therapeutic drug monitoring in a home care setting.

Study design

In the proposed study IBD patients that are treated with infliximab will be asked to participate. A total of two blood samples will be taken from the patients: pre- infusion and four weeks before/after infusion (the scheduled time interval between two infusions is eight weeks). This will necessitate one extra visit to the clinic for the four week sample. Blood samples will be analyzed for serum infliximab levels by two methods: 1) standard ELISA test and 2) rapid assay format for multiplex detection (*lab on chip*). Results of both analyses will be compared.

Study burden and risks

Burden: one extra venapuncture at week 4. No risk or imediate benefit.

Contacts

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Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Crohn's disease, infliximab therapy

Exclusion criteria

None

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):	04-12-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2009
Application type:	First submission
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	NL26052.058.08