Validation of dried blood samples for adalimumab in IBD-patients

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

Summary

ID

NL-OMON46650

Source
ToetsingOnline

Brief title
DBS validation adalimumab

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Adalimumab, Dried Blood Sample, IBD

Outcome measures

Primary outcome

Primary: to investigate feasibility of DBS from finger prick for measuring adalimumab drug levels and antibodies-to-adalimumab compared with the results of venepuncture serum sample measurements.

Secondary outcome

To compare levels of albumin and CRP from DBS with the results of venepuncture serum sample measurement and to investigate feasibility of DBS from finger prick at home.

Study description

Background summary

Higher adalimumab serum concentrations are associated with increased rates of clinical response, and endoscopic healing. The use of anti-TNF therapy is however complicated by loss of response (LOR). The exact mechanism behind LOR is unknown, but it is likely that an increased clearance of anti-TNF plays a role. One of the factors influencing clearance is the formation of antidrug-antibodies, in this case antibodies-to-adalimumab. In recent years it has become clear that therapeutic drug monitoring (TDM) can be an important tool to optimize outcome of anti-TNF treatment. The dried blood spot sample (DBS) method with blood obtained via a finger prick greatly facilitates TDM, since patients can administer this finger prick themselves at any time. Therapeutic monoclonal antibodies and antidrug-antibodies can be accurately quantified in DBS and anti-TNF measurements in DBS have been previously described in patients with inflammatory bowel disease treated with infliximab or adalimumab (n=20).

Study objective

The aim is to investigate the feasibility of DBS from finger prick for

measuring adalimumab drug levels and antibodies-to-adalimumab compared with the results of venepuncture serum sample measurements. As a secondary objective, measurements of albumin and CRP will also be compared between both methods. Also, feasibility of DBS from finger prick at home will be investigated.

Study design

A longitudinal study of 75 patients with Inflammatory Bowel Disease (IBD) receiving adalimumab induction or maintenance treatment. Blood via venepuncture and DBS via finger prick will be obtained simultaneously from each patient by a trained employee. DBS will be obtained by the patient himself at the visit to the outpatient clinic and at home to test the feasibility of DBS at home.

Study burden and risks

During a regular hospital visit a venepuncture and a finger prick for DBS will be performed at the same visit by a trained employee. Additional DBS will be obtained by the patient at the outpatient clinic visit and by the patient himself at home.

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 of female
Diagnosis of IBD
Receiving adalimumab therapy

Exclusion criteria

Contra-indication to adalimumab (TBC, severe infections or congestive heart failure)

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):	22-03-2018
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	13-03-2018
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	NL64574.018.18