Validation of a finger prick capillary blood sampling test for home monitoring of C-reactive protein and therapeutic drug monitoring of biological therapy in patients with inflammatory bowel disease

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

Summary

ID

NL-OMON51794

Source
ToetsingOnline

Brief title
FiP-HOME-IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Chronic bowel disease, Inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Sanquin Bloedbank,Study financed by Gastroenterology department of UMCG. Sandquin diagnostic laboratories provides in kind contribution (Finger prick kit;transport of samples;analysis of samples)

Intervention

Keyword: Biological, C-reactive Proteine, Home Monitoring, Inflammatory Bowel Disease

Outcome measures

Primary outcome

Concentrations of CRP and pharmacodynamic and pharmacokinetic domains of

biological therapy (i.e., concentration of biological trough levels,

concentration of antidrug antibody levels) measured in capillary samples

compared to venous samples (standard procedure)

Secondary outcome

-Percentage of patients unable to provide a capillary sample

-Patience experience of capillary sampling through finger prick at home,

invistigated through a survey

Study description

Background summary

Biological therapy has become the mainstay of treatment for patients affected by Inflammatory Bowel Diseases (IBD). Monitoring of C-reactive protein (CRP) and Therapeutic Drug Monitoring (TDM) of biological therapy provides important guidance for the treating physician and the clinical pharmacist. CRP monitoring and TDM aims to identify over- and undertreatment, indentify anti-drug-antibodies (ADA) and allows for dose adjustments or switches to alternative treatment regimens. CRP monitoring and TDM while leveraging a

finger prick blood sampling technique in a home setting would allow caregivers to closely monitor drug levels and anti-drug antibodies and thereby optimize biological therapy for patients with IBD. Most importantly, however, it does not require IBD patients to travel to hospitals, which forms a valuable servic

Study objective

The primary objective of this study is to validate a capillary blood sampling technique which can be individually performed by patients themselves in a home-setting using a finger prick test. This test enables simultaneous monitoring of systemic inflammation (CRP) and drug levels (TDM) in patients with IBD who receive biological therapy at home.

Study design

A prospective observational single-center study involving Crohn's disease (CD) and ulcerative colitis (UC) patients. Concentrations of CRP and biological trough levels as well as anti-drug antibodies (ADA) will be determined in capillary blood samples obtained through finger prick tests, which will compared to concentrations in serum obtained by a routinely performed venipuncture. At the same day that patients will receive in-hospital biological infusion, patients will be requested to deliver both a blood sample through routine venipuncture and a finger prick test performed at home. Samples will be sent to Sanquin Diagnostics Laboratory to perform the laboratory analysis.

Study burden and risks

Burdens and risks of this study are solely associated with the capillary blood sampling technique using a finger prick device. Administration of biological therapy and routinely performed venipunctures are standard of care.
Patients will be asked to perform a single finger prick to obtain capillary blood samples. More specifically, they will be requested to provide 5 drops of blood (+/- 200 microliters).
Despite the novelty of this capillary sampling technique using a finger prick device, the protocol through which these blood samples will be acquired (using the finger prick device) is already well-established in clinical care. For instance, patients with diabetes mellitus extensively use finger prick devices at home to monitor their blood glucose levels. Taking these common practices into consideration, the widespread use of finger prick devices is thoroughly documented and the clinical usage of these devices has become common nowadays.
A finger prick method constitutes a minimally invasive procedure with very rare chances of potential complications. The most common patient complaint is pain at the place of puncture after the finger prick, which can however be largely avoided by providing adequate instructions to patients, minimizing chances of pain sensations.
This study will not provide a direct benefit to participating patients, but the

results of this study will be key to facilitate and optimize biological therapy at home, thereby effectively reducing disease burden of patients, and, ultimately, also that of the IBD healthcare system

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

- An established diagnosis of Crohn's disease (CD) or ulcerative colitis (UC)
- Receiving biological induction or maintenance therapy according to standard treatment protocols
- 18 years of age or older
- Written and signed informed consent

Exclusion criteria

- Patients with a visual, physical or mental impairment, rendering them unable to use a capillary sampling device.
- Patients unable to read or understand the Dutch language
- Patients with severe Raynaud*s syndrome or digital ischemia
- Unwillingness to participate in the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2022
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-04-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL79783.042.21