

SELFIE study: Home or hospital-based analysis of stool calprotectin

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24517

Source

Nationaal Trial Register

Brief title

SELFIE-study

Health condition

Inflammatory bowel disease, IBD, Crohn's disease, Ulcerative colitis

Sponsors and support

Primary sponsor: University Medical Centre Groningen (UMCG)

Source(s) of monetary or material Support: Bühlmann Laboratories AG, Switzerland

Intervention

Outcome measures

Primary outcome

Agreement between IBDocTM result and the Quantum Blue result.

Secondary outcome

Agreement between IBDocTM at home and the result performed in the lab with the same

extraction solution.

Study description

Study design

12 months

Intervention

In this study we want to compare the established Quantum Blue® method for measuring calprotectin with the new IBDoc™ home-monitoring method. We wish to see whether they agree sufficiently for the new to replace the old.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible patients are those aged 12 to 19 years, with IBD diagnosed (according to the Porto criteria) more than 6 months before enrolment, who have a smartphone with access to internet, knowledge of the Dutch language, and an adult caregiver who is willing to actively support participation.

Exclusion criteria

Patients will be excluded from the study when they have an ileostomy (as calprotectin cut-offs are not validated for small bowel feces), or when they are taking medication that may influence stool calprotectin levels (NSAIDs).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	23-03-2015
Application type:	First submission

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
NTR-new	NL4987
NTR-old	NTR5133
Other	MEtc UMCG : 2014.466.

Study results

Summary results

N/A