

# **ALERT: Validation of an 8-item questionnaire predictive for a positive Calprotectin test and Real-life implementation in primary care to reduce diagnostic delay in inflammatory bowel disease**

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<b>Registration date</b> 13/11/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## **Plain English summary of protocol**

### Background and study aims

Diagnosing inflammatory bowel disease (IBD) in primary care (for example, within a GP surgery) is challenging and a diagnosis can take a long time to confirm. This delay can result in a worsening of the condition and disease outcome. Although testing for fecal Calprotectin (inflammation of the bowel) is a useful screening tool to identify patients who need endoscopy for IBD, it is not routinely used in primary care. Here, we want to test an 8-item-questionnaire, the CalproQuest, which aims to identify those patients most likely to have IBD and therefore in need of a fecal Calprotectin test. We want to know whether the CalproQuest works and whether it is feasible in primary care setting.

### Who can participate?

The study consists of two parts 1 and 2, conducted by gastroenterologists and general practitioners (GPs), respectively. Patients included in part 1 of the study are referred for endoscopic evaluation to gastroenterologists specialised for IBD. Patients included in part B of the study present at their GP because of ongoing unspecific gastrointestinal symptoms (abdominal pain, bloating, stool irregularities, diarrhea) for at least two weeks.

### What does the study involve?

Part 1: Patients fill out the CalproQuest questionnaire and their stool is tested for Calprotectin. They then undergo a endoscopic examination. Eventually, patients diagnosed with IBD will be asked to complete a questionnaire investigating how long it took for the diagnosis to be confirmed.

Part 2: Patients going to their GP with ongoing unspecific gastrointestinal symptoms for more than two weeks are asked to fill in the CalproQuest and provide stool samples for Calprotectin testing. Patients who have high Calprotectin levels are referred to a gastroenterologist for endoscopic examination. The results are then sent back to the GP. Patients are then asked to

complete a questionnaire on acceptance of stool sampling, and physicians will complete the questionnaire on the feasibility of using CalproQuest in daily practice.

What are the possible benefits and risks to participating?

The patients have the benefit of a systematic questionnaire with key questions addressing early symptoms of IBD. In Part 1 an endoscopy is performed, but on patients that have already been referred for endoscopic evaluation. Therefore, no additional risks are expected.

Where is the study conducted?

The University of Zurich (Switzerland).

When is the study starting and how long is it expected to run for?

October 2014 to March 2016.

Who is funding the study?

1. Institute for Primary Care University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switzerland)
2. IBDnet (Switzerland)

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

ALERT: VALidation of an 8-item questionnaire predictive for a positive Calprotectin test and Real-life implementation in primary care to reduce diagnostic delay in inflammatory bowel disease: a prospective diagnostic observational trial

### Acronym

ALERT

### Study objectives

This study pursues two main aims A and B, which are investigated independently:

1. Prospective validation and evaluation of sensitivity and specificity of an 8-item inflammatory-bowel-disease (IBD)-questionnaire (CalproQuest) for 1) a positive Calprotectin test result  $50 \mu\text{g/g}$  feces and for 2) a positive Calprotectin test result  $50 \mu\text{g/g}$  feces and positive IBD-diagnosis, respectively, in tertiary care
2. Prospective implementation of CalproQuest in primary care to investigate feasibility in daily practice

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The ethics board of the Canton Zurich (Kantonale Ethik-Kommission Zürich), 25/06/2014, ref. KEK-ZH-Nr. 2013-0516

### Study design

Prospective diagnostic observational trial

### Primary study design

Observational

### Secondary study design

Cohort study

### Study setting(s)

Other

### Study type(s)

Diagnostic

### Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Immune bowel disease

## Interventions

1. Investigation of the sensitivity and specificity of CalproQuest for stool Calprotectin levels  $\geq 50$   $\mu\text{g/g}$  feces and for positive IBD diagnosis:

Patients referred to the gastroenterologist for endoscopic examination are subjected to CalproQuest and Calprotectin stool testing prior endoscopy. At baseline T0, patients will be subjected to CalproQuest. Subsequently, at T1 fecal samples will be obtained to measure Calprotectin levels. The patients themselves will perform collection of the fecal specimens. The fecal specimens from outpatients will be shipped to the laboratory at the University Hospital Zurich by mail. After measurement, fecal samples will be disposed according to current guidelines. At T2, endoscopic examination will be performed to obtain a diagnosis. Eventually, patients diagnosed with IBD will be asked to complete a questionnaire at T3 investigating duration of first onset of symptoms to IBD diagnosis (diagnostic delay).

2. Investigation of feasibility of CalproQuest in daily primary care practice

Patients with on-going unspecific gastrointestinal symptoms (abdominal pain, bloating, stool irregularities, diarrhea) for more than two weeks presenting at the GP will be included into the study if all inclusion criteria are met and informed patient consent is obtained. At baseline (T0), patients will be subjected to CalproQuest. Subsequently, at T1 fecal samples will be obtained to measure Calprotectin levels. The patients themselves will perform collection of the fecal specimens. The fecal specimens will be shipped to the laboratory at the University Hospital Zurich by mail. After measurement, fecal samples will be disposed according to current guidelines. According to the current standard of care it is recommended to refer patients with Calprotectin levels  $\geq 50$   $\mu\text{g/g}$  to a gastroenterologist for endoscopic examination at T2; results of the endoscopy are communicated back to the GP. Patients will be asked at T3 to complete a questionnaire on acceptance of stool sampling, and physicians will complete the questionnaire on feasibility of CalproQuest in daily practice.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

Part 1:

1.1. Sensitivity and specificity of CalproQuest for a positive Calprotectin test result  $50$   $\mu\text{g/g}$  feces

1.2. Sensitivity and specificity of CalproQuest for a positive Calprotectin test result  $50$   $\mu\text{g/g}$  feces and positive IBD-diagnosis.

Part 2:

2.1 Feasibility of CalproQuest in daily primary care practice

Timepoints:

Part 1: Sensitivity and specificity (primary outcomes) will be measured 12 months after recruiting the last study centre (part 1: IBD-centre, part 2: GP) or earlier, when the target number of patients (part 1: 162, part 2: 80) has been achieved.

Part 2: Feasibility of CalproQuest in daily primary care practice will be measured after the announcement of the Calprotectin test result, not exceeding 2 weeks after the consultation at the gastroenterologist or GP.

## Secondary outcome measures

Part 1: Patient-reported diagnostic delay.

Part 2: Patient acceptance of stool sampling.

**Timepoints:**

Part 1: Patient-reported diagnostic delay after the endoscopy exam, the whole procedure between first consultation and endoscopy will take at most 2 months.

Part 2: Patient acceptance of stool sampling directly after fecal samples will be obtained at home (not exceeding 2 weeks after the consultation at the gastroenterologist or GP).

**Overall study start date**

14/10/2014

**Completion date**

31/03/2016

## **Eligibility**

**Key inclusion criteria**

1. Are aged at least 18 years (part 1, 2)
2. Are referred to their gastroenterologist for any endoscopic examination (part 1)
3. Visit their GP because of on-going unspecific gastrointestinal symptoms (abdominal pain, bloating, stool irregularities, diarrhea) for at least two weeks (part 2)
4. Underwent no earlier diagnostic procedures (endoscopy) for the current episode (part 2)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

162 patients in part 1, 80 patients in part 2

**Key exclusion criteria**

1. Are younger than 18 years (part 1, 2)
2. Have known further /other abdominal pathologies as e.g. cancer (part 1, 2)
3. Had previous abdominal surgeries (part 2)
4. Have been treated with steroids (topical and/or oral) and/or aminosalicylates within 30 days prior inclusion into this study (part 2)
5. Underwent endoscopic examination within 3 years prior screening (part 2)

**Date of first enrolment**

14/10/2014

**Date of final enrolment**

31/03/2016

# Locations

## Countries of recruitment

Switzerland

## Study participating centre

Institute of Primary Care

Zürich

Switzerland

8091

# Sponsor information

## Organisation

University Hospital of Zurich (Switzerland)

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/01462r250>

# Funder(s)

## Funder type

Other

## Funder Name

Institute for Primary Care University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switzerland)

**Funder Name**

IBDnet (Switzerland)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	10/03/2015		Yes	No