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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

Submission date	**Recruitment status**	[_] Prospectively registered
31/10/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/11/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2020	Digestive System	[_] 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

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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 pursuits 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 µg/g feces and for 2) a positive Calprotectin test result 50 µg/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 ≥ 50 µg/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 ≥ 50 µg/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 µg/g feces
1.2. Sensitivity and specificity of CalproQuest for a positive Calprotectin test result 50 µg/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)

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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?
Protocol article	protocol	10/03/2015		Yes	No