Cost-Effectiveness of a diagnostic Decision rule for patients with lower Abdominal complaints in primary caRe.

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The aim of the study is to quantify the accuracy and cost-effectiveness of a diagnostic decision rule for OBD, in patients with persisting lower gastro-intestinal complaints in primary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37021

Source
ToetsingOnline

Brief title
The CEDAR-study.

Condition

- Other condition
- Gastrointestinal inflammatory conditions

Synonym
organic diseases of the lower gut, spastic colon (for functional bowel disease)

Health condition

alle organische ziekten van het onderste maagdarmstelsel

Research involving
Human

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZON)
Source(s) of monetary or material Support: ZonMw;Doelmatigheid

Intervention

Keyword: clinical decision rule, functional bowel disease, lower gastro-intestinal complaints, organic bowel disease

Outcome measures

Primary outcome

The primary outcome is the presence of OBD at endoscopy. The diagnostic accuracy of symptoms and signs and the added value of the different tests - notably the calprotectine test- for OBD are quantified. The most cost-effective strategy to discriminate the patients at high risk (requiring a fast track diagnostic workup) from those at low risk (not requiring endoscopy) will be identified.

Secondary outcome

See primary study parameters.

Study description

Background summary

Lower gastro-intestinal (GI) tract complaints are frequently presented in primary care. About 7% of these patients has organic bowel disease (OBD), such as Inflammatory Bowel Disease or Colorectal Cancer. Most have functional disease (FBD), such as Irritable Bowel Syndrome. Adequate discrimination is important, as both unnecessary endoscopy as well as delayed detection of OBD is burdening and costly. Presently up to 20% of patients with persisting GI complaints is referred for endoscopy, but only in one-third OBD is found. The diagnostic process in primary care needs improvement. Symptoms alone cannot identify OBD accurately, but new point-of-care faecal biomarker tests for inflammation are promising. This study aims to identify the most cost-effective

diagnostic strategy to estimate the absence or presence of OBD in patients with lower intestinal complaints, combining history, physical examination, blood tests, an immunochemical fecal occult blood test and a faecal calprotectine test.

Study objective

The aim of the study is to quantify the accuracy and cost-effectiveness of a diagnostic decision rule for OBD, in patients with persisting lower gastro-intestinal complaints in primary care.

Study design

This diagnostic cohort study in primary care includes all patients with lower GI tract complaints longer than 2 weeks, in whom referral for endoscopy is indicated because of increased risk of OBD. All patients undergo history taking and physical examination. In addition biochemical parameters (ESR, CRP, Hb, leucocytes and anti-tTG antibodies), an immunochemical fecal occult blood test and a point-of-care calprotectine test are determined. Patients will be referred for endoscopy. After the endoscopy, subjects will be asked to fill out the three questionnaires once more for follow-up and the results of the endoscopy will be obtained.
Participation of 110 practices is required to include 990 patients referred for lower intestinal endoscopy, of whom 300 patients will have OBD.The project will require 36 months (3 months for preparation and recruitment of practices, 30 months for inclusion and follow-up and 3 months for data-analysis and reporting results).

Study burden and risks

Beside the usual care -conform existing guidelines- of history taking and physical examination, the burden of patients for participation notably exists in answering additional questions about their complaints and quality of life (twice), a blood sample and collecting a fecal sample prior to the endoscopy. The study has no influence on the diagnostic or therapeutic strategy of the practising physician.

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

Patients with non-acute (> 2 weeks) abdominal complaints originating from the lower GI tract and with at least one of the following criteria (high risk patients):
- unexplained rectal blood loss
- unexplained weight loss
- unexplained abdominal pain
- persistant diarrhoea
- altered defecation pattern
- unexplained fever
- sudden onset in elderly patients
- abnormal results at physical examination

Exclusion criteria

Being unable to give informed consent
Age under 18 years
A history of OBD
Contra-indications for endoscopy
Patients with a positive Triple Faeces Test (TFT-test), a test for detection of intestinal parasites.

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):	17-07-2009
Enrollment:	990
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	30-03-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25319.041.08