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Capsule colonoscopy option increases uptake of colorectal cancer screening

Submission date	Recruitment status	[ ] Prospectively registered
21/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2014	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Colorectal cancer screening is used to detect cancer at an early stage, before symptoms start to appear. It is done because treating the disease is more successful if its caught at an early stage. Endoscopy is an effective method of exploring the bowel for signs of cancer. A thin, flexible tube with a tiny camera attached is placed into the bowel. The medical team is then able to see the inside of the bowel though images sent to a television screen. Despite its success, many people who would otherwise benefit from the procedure (i.e. people over the age of 55) are reluctant to take part due, in part, to it being thought of as unpleasant. Capsule endoscopy is a new method which is painless and involves swallowing a small pill-like video camera which travels through the bowel and takes images. It is thought that capsule endoscopy might encourage more people to undergo colorectal cancer screening. This study aims to explore whether inviting people to undertake endoscopic screening for colorectal cancer and offering the new capsule endoscopy will persuade more people to go for screening compared to those offered conventional endoscopy.

Who can participate?
People over the age of 55 who are insured with BKK 24 in the area of Rintein/Lower Saxonia (Germany)

What does the study involve?
The participants receive an invitation letter for colorectal cancer screening by either conventional or capsule endoscopy. The participants then respond if they want to undergo the procedure.

What are the possible benefits and risks of participating?
The study per se only measures uptake. The risks of the endoscopic procedures are well known and will be communicated in the informed consent

Where is the study run from?
Rinteln, Lower Saxonia, Germany

When is study starting and how long is it expected to run for?
March 2009 to July 2011

Who is funding the study?
Given Imaging Ltd (Germany)

Who is the main contact?
Prof. Dr. Thomas Rösch
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CRCS Uptake study 1

Study information

Scientific Title
Capsule colonoscopy option increases uptake of colorectal cancer screening: a prospective regional study in Germany

Study objectives
Capsule colonoscopy increases uptake as compared to conventional colonoscopy when offered to persons eligible for colorectal cancer screening

Ethics approval required
Old ethics approval format

Ethics approval(s)
International Medical & Dental Ethics Commission (IMDEC) GmbH Ethical Committee, Freiburg approved on 31st March 2009

Primary study design

Interventional

Study design
Prospective single arm study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colorectal cancer screening

Interventions
2150 participants receive an invitation letter for colorectal cancer screening by either conventional or capsule endoscopy. The pros and cons of each are briefly described and can be further discussed with four gastroenterologists who are named in the letter. Follow-up is 1-2 weeks after capsule and/or conventional colonoscopy.

The practical part of the study took part in 2009. It took until the end of last year to collect all the data from private practice physicians (time constraints for audits).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Uptake of capsule and conventional endoscopy after invitation (measured whenever patients react to the letters, usually within a few weeks) as compared to spontaneous uptake in the same area in the preceeding years

Key secondary outcome(s)
1. Adenoma yield in both groups, namely the capsule group including those participants with subsequent colonoscopy, and the group with capsule colonoscopy only
2. Rate of capsule examinations with sufficient bowel preparation (grading was done on a 4-point scale in accordance with previous studies
3. Adverse events and complications in both arms of the study
4. Patient opinion and acceptability according to the questionnaires

Measured during or after (2 weeks) performance of either conventional and/or capsule endoscopy

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Persons over 55 years of age eligible for screening insured with BKK 24 in the area of Rinteln /Lower Saxonia (Germany) are invited by a letter sent out from BKK 24 medical insurance during

2009 to participate in screening using either capsule or conventional colonoscopy.
2. Interested persons are informed by four gastroenterologists and one of the tests will then be performed at screnees choice

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Symptomatic persons
2. Persons having undergone screening colonoscopy

Date of first enrolment
01/03/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Germany

Study participating centre
Department of Interdisciplinary Endoscopy
Hamburg
Germany
20246

Sponsor information

Organisation
Given Imaging Ltd. (Germany)

ROR
https://ror.org/00fdh5j55

Funder(s)

Funder type
Industry

Funder Name
Given Imaging Ltd. (Germany)

Funder Name
BKK 24 Medical Insurance Company (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration