# Capsule colonoscopy option increases uptake of colorectal cancer screening

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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 t.roesch@uke.de

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Thomas Rösch

#### Contact details

Department of Interdisciplinary Endoscopy University Hospital Hamburg Eppendorf Martinistr. 52 Hamburg Germany 20246 t.roesch@uke.de

# 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

# Study design

Prospective single arm study

### Primary study design

Interventional

### 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

# **Study outputs**

Output type Date created Date added Peer reviewed? Patient-facing? **Details** Participant information sheet 11/11/2025 No

Participant information sheet Yes