

# Capsule colonoscopy option increases uptake of colorectal cancer screening

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<b>Registration date</b> 28/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/06/2014	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Rinteln/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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

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

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/03/2009

**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 screenees choice

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

2150

**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)

### **Sponsor details**

c/o Manfred Gehrtz  
Borsteler Chaussee 47  
Hamburg  
Germany  
22453  
Manfred.Gehrtz@givenimaging.com

### **Sponsor type**

Industry

### **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**

**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