# Evaluation of PillCam* Colon 2 in Visualization of the colon

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Evaluate accuracy of PillCam* COLON 2 system in detecting patients with colonicpolyps *6mm and *10 mm as compared to conventional colonoscopy.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON34767

**Source**
ToetsingOnline

**Brief title**
Evaluation of PillCam* Colon 2

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

**Synonym**
colorectal adenomas, Colorectal polyps

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** GIVEN IMAGING LIMITED
**Source(s) of monetary or material Support:** GIVEN IMAGING Ltd

## Intervention

**Keyword:** Colon, Colorectal polyps, Video capsule endoscopy

## Outcome measures

### Primary outcome

Accuracy parameters of PillCam* COLON 2 in detecting patients with colonic polyps *6mm and *10 mm as compared to conventional colonoscopy.

### Secondary outcome

1) Diagnostic yield of PillCam* COLON 2 in detecting colonic lesions as compared to conventional colonoscopy

2) Assessment of colon cleansing level at different colon segments for PillCam and Colonoscopy

3) Distribution of capsule excretion time up to 10 hours post ingestion based on Rapid videos

4) Capsule transit time within stomach, small bowel and colon based on Rapid videos

5) Prevalence of polyps at different size categories and locations as detected by capsule

6) Prevalence of polyps at different size categories and locations as detected by conventional colonoscopy

7) RAPID reading time

8) Number, type and severity of adverse events

# Study description

### Background summary

Colorectal cancer (CRC) is one of the most common cancers in western countries. Appropriate screening and surveillance could not only reduce the morbidity and mortality of CRC but also its incidence. Conventional colonoscopy (CC) is considered to be the best available method for the detection of adenomas and CRC. However, this is an invasive and costly procedure, associated with a procedural risk. The ideal test for screening and surveillance purposes should be safe, less invasive and cheaper than CC, and with a high diagnostic accuracy. Following the success of the small bowel capsule endoscopy, colon capsule endoscopy (CCE) might be an attractive alternative for colon screening and surveillance.

### Study objective

Evaluate accuracy of PillCam* COLON 2 system in detecting patients with colonic polyps *6mm and *10 mm as compared to conventional colonoscopy.

### Study design

This study will evaluate the performance of PillCam* COLON 2 in visualization of the colon as compared to conventional colonoscopy.
Up to 130 subjects will participate in this study. All subjects to be enrolled in this study are indicated and scheduled to undergo colonoscopy based on their clinical indication with no relation to the tested device. Each subject will undergo examination by the PillCam Colon and conventional colonoscopy procedure. The generated RAPID video will be reviewed by a physician blinded to the results of the conventional colonoscopy and vice versa (the Colonoscopist will be blinded to the capsule*s results). Finally the PillCam* COLON 2 results will be compared with conventional colonoscopy results that will be regarded as the *gold standard*. In cases of which capsule will detect significant finding (polyp*6mm) and colonoscopy will be either normal or show only insignificant findings, the subjects will be offered a 2nd colonoscopy to verify and remove the polyp that was initially detected by the capsule. In addition, procedures outcome will be analyzed with regard to the study objectives and end points.

### Study burden and risks

A risk of videocapsule endoscopy is retention of the capsule. In patients without (suspected) intestinal stenosis or obstruction this risk is negligible. To date no adverse events were reported with CCE.

As for the conventional colonoscopy, colon preparation with laxatives and an adjusted diet is needed for colon capsule endoscopy. In this study the conventional colonoscopy will be performed as soon as the capsule has left the body or the battery is empty (after 10 hours). The conventional colonoscopy will be performed the same day or at last the next morning. Only in the last case extra laxatives are needed to keep the colon well prepared for the conventional colonoscopy.

## Contacts

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Israel
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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 referred to colonoscopy for at least one of the following reasons:
- Colorectal cancer screening for age *50
- Clinical symptoms such as: rectal bleeding, hematochezia, melena, positive FOBT, recent change of bowel habits for age *50
- Positive findings in the left colon during sigmoidoscopy(e.g. Polyp *10mm)
- Personal history of polyps that were removed at least 3 years ago

## Exclusion criteria

1. < 18years, > 80 Years
2. Subject has dysphagia or any swallowing disorder
3. Subject has congestive heart failure
4. Subject has high risk of renal insufficiency associated with the use of sodium phosphate
5. Subject is not eligible for colon preparation due to the presence of underlying conditions based on the clinical judgment of the investigator
6. Subject has any allergy or other known contraindication to the medications used in the study
7. Surgical intestinal anastomosis
8. Subject has a cardiac pacemaker or other implanted electro medical device.
9. Subject is expected to undergo MRI examination within 7 days after ingestion of the capsule.
10. Known or suspected gastro-intestinal obstruction
11. Subject has known delayed gastric emptying
12. Women who are either pregnant at the time of screening, or are of childbearing potential and do not practice medically acceptable methods of contraception.
13. Subject currently participating in another clinical study
14. No informed consent, or inability to understand patient information and/ or give informed consent.

# Study design

## Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2010 |
| Enrollment: | 16 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL30940.018.09 |