



PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Investigation of the analysis quality of PillCam Colon Capsule endoscopy of Doctors and Nurses compared to experts - RCT.

Trial Acronym

[---]*

URL of the trial

http://-

Brief Summary in Lay Language

The topic of the study is the investigation of the analysis quality of Colon capsule endoscopy of Doctors and endoscopy nurses compared to results of experts. (Golden Standard). Studies about small bowel capsule endoscopy (PillCam SB) have a high agreement between doctors and nurses (Bossa et al. [2006], Niv & Niv [2005] und Levinthal et al. [2003]; 85%, 96,9% bzw. 93%). A German or international study about the investigation of the analysis quality of PillCam Colon Capsule endoscopy with doctors and nurses compared to experts doesn't exist yet. We form pairs of analysers in all 9 study centres. In every centre a doctor and a nurse interpret same 30 randomized colon capsule films. Participants are 9 physicians and 9 endoscopy nurses from several hospitals in Germany. The participants don't know the results and don't know who is he copartner of the pair. The primary endpoint of the study is the proof to a comparable high sensitivity. Secondary endpoints are:

- a. comparison of the specificity of the detection of polyps of doctors and nurses comparing to the results of experts (Golden Standard).
- b. comparison of the number of polyps between doctors and nurses
- c. comparison of the polyp size (≥ 10 mm) between doctors and nurses
- d. comparison of the needed time for analysis between doctors and nurses
- f. Comparison of the years of occupation and the number of both carried out and assisted colonoscopies between doctors and nurses

Brief Summary in Scientific Language

The topic of the study is the investigation of the analysis quality of Colon capsule endoscopy of Doctors and endoscopy nurses compared to results of experts. (Golden Standard). Studies about small bowel capsule endoscopy

(PillCam SB) have a high agreement between doctors and nurses (Bossa et al. [2006], Niv & Niv [2005] und Levinthal et al. [2003]; 85%, 96,9% bzw. 93%). A German or international study about the investigation of the analysis quality of PillCam Colon Capsule endoscopy with doctors and nurses compared to experts doesn't exist yet. We formed pairs of analysers in all 9 study centres. In every centre a doctor and a nurse interpret same 30 randomized colon capsule films. Participants are 9 physicians and 9 endoscopy nurses from several hospitals in Germany. The participants don't know the results and don't know who is the other part of the pair. The primary endpoint of the study is the proof to a comparable high sensitivity. Secondary endpoints are:

- a. comparison of the specificity of the detection of polyps of doctors and nurses comparing to the results of experts (Golden Standard).**
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- f. Comparison of the years of occupation and the number of both carried out and assisted colonoscopies between doctors and nurses**

Organizational Data

- DRKS-ID: **DRKS00000324**
- Date of Registration in DRKS: **2010/05/25**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **HRB 5865 , International Medical and Dental Ethics Commission GmbH Freiburg im Breisgau**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1115-0107**

Health condition or Problem studied

- Free text: **Analysis of interpretation quality of PillCam Colon- Capsule endoscopy films by different medical staff compared to experts**

Interventions/Observational Groups



- Arm 1: **Group A include 9 endoscopy nurses or nurse assistants who assisted at least 300 colonoscopies independent. All 9 study participants in group A have to analyse 30 randomized capsule endoscopy films.**
- Arm 2: **Group B include 9 physicians who have done at least 300 colonoscopies independent. All study participants in group B have to analyse 30 randomized capsule endoscopy films.**

Interpretation pairs have been buildt between group A and B. So every pair analyse the same 30 randomized films but not in the same centre.

- Arm 3: **The Golden Standard is the documented result of the interpretation of colon capsule endoscopy by 14 experts from several european countries. All 14 experts are internists and gastroenterologists and have done at least 500 colonoscopies independent. They have experience in capsule endoscopy and have got a special training in colon capsule endoscopy.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

The primary endpoint of the study is the proof to a comparable high sensitivity between nurses and physicians compared to experts.

Secondary Outcome

Secondary endpoints are:

- a. **comparison of the specifity of the detection of polyps of doctors and nurses comparing to the results of experts (Golden Standard).**
- b. **comparison of the number of polyps between doctors and nurses**
- c. **comparison of the polyp size (=> 10 mm) between doctors and nurses**
- d. **comparison of the needed time for analysis between doctors and nurses**
- f. **Comparison of the years of occupation and the number of both carried out and**

assisted colonoscopies between doctors and nurses

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/05/25**
- Target Sample Size: **18**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Included have been nurses who should have completed further education in endoscopy nursing and physicians who should be at least general practitioner (internist). Both staff should have experience with at least or more 300 colonoscopies which should be done independent and both staff groups shouldn't have experience in capsule endoscopy

Exclusion criteria

Excluded have been nurses who do not have further education in endoscopy nursing and who physicians do not have an examen for general practitioner (internist). Both staff groups have less experience then 300 colonoscopies and have already experience in capsule endoscopy



Addresses

■ Primary Sponsor

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URL: [---]*

Sources of Monetary or Material Support

■ Commercial (pharmaceutical industry, medical engineering industry, etc.)

Given Imaging GmbH
EMA Headquaters

Given Imaging Ltd.
New Industrial Park
Yoqneam/ Israel
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Commercial (pharmaceutical industry, medical engineering industry, etc.)

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■ **Institutional budget , no external funding (budget of sponsor/PI)**

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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.