ISRCTN70400953 https://doi.org/10.1186/ISRCTN70400953

Comparison of precancerous lesions detection between standard colonoscopy and novel balloon colonoscopy

Submission date
17/12/2014

Recruitment status
No longer recruiting

Registration date
14/01/2015

Overall study status
Completed

Last Edited
10/04/2019

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A colonoscopy is a procedure used to examine the large bowel, the colon or the rectum. Colorectal cancer can be diagnosed using this type of procedure. The procedure involves the use of a device called a colonoscope. This study compares two devices and the aim is to assess which device will detect the highest number of precancerous lesions.

Who can participate?
Adult healthy volunteers over 50 referred for colonoscopy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 undergo a colonoscopy using a standard colonosope. Those in group 2 undergo a colonoscopy using a G-EYE HD colonoscope.

What are the possible benefits and risks of participating?
Based on previous studies, use of the G-EYE colonoscope leads to improved detection of adenomas and serrated lesions. The G-EYE colonoscope is CE marked and used like any other colonoscope. Any complications that may result from the procedure are the same as those associated with a standard colonoscopy.

Where is the study run from?
A number of hospitals in Europe, Israel, India and the USA

When is the study starting and how long is it expected to run for?
May 2014 to January 2018

Who is funding the study?
Smart Medical Systems Ltd (Israel)

Who is the main contact?
Ms Avda Yoelzon

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01917513

Protocol serial number
G-EYE15505

Study information

Scientific Title
Prospective randomized trial to compare the clinical efficiency (Adenoma Detection Rate) of G-EYE™ HD Colonoscopy with Standard HD Colonoscopy

Study objectives
G-EYE™ HD colonoscopy detects substantially more adenomas and serrated lesions compared with Standard HD colonoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Landesarzlekammer Hessen Ethics Committee, 13/01/2014, ref: FF133/2013

Study design
Randomized interventional multicentre open-label trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
The trial contains two arms:
1. Investigational arm: G-EYE™ colonoscopy
2. Control arm: standard colonoscopy

Intervention Type
Device

Primary outcome(s)
Adenomas and serrated lesions detection rate: the percentage of subjects with at least one adenoma or serrated lesion found in each of the study groups. Timepoint: up to 14 days following procedure (histology results)

Key secondary outcome(s))
1. Polyp and adenoma detection: number of polyps and adenomas detected. Timepoint: up to 14 days following procedure (histology results)
2. Procedural times: minutes. Timepoint: During the procedure
3. Safety: number and severity of adverse events. Timepoint: During the procedure, post procedure, during follow-up calls or during unscheduled visits of the subjects

Completion date
23/10/2017

Eligibility

Key inclusion criteria
1. Patients over 50
2. Referred to colonoscopy for screening, following positive Fecal Occult Blood Test (FOBT) testing, change of bowel habits or for surveillance colonoscopy (history of adenoma resection)
3. The patient must understand and provide written consent for the procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subjects with inflammatory bowel disease
2. Subjects with a personal history of polyposis syndrome
3. Subjects with suspected chronic stricture potentially precluding complete colonoscopy
4. Subjects with diverticulitis or toxic megacolon
5. Subjects with a history of radiation therapy to abdomen or pelvis
6. Pregnant or lactating female subjects
7. Subjects who are currently enrolled in another clinical investigation.
8. Subjects with current oral or parenteral use of anticoagulants
9. Subjects with recent (within the last 3 mounts) coronary ischemia or CVA (stroke)
10. Any patient condition deemed too risky for the study by the investigator
11. Previous colonic surgery (except for appendectomy)

Date of first enrolment
26/05/2014

Date of final enrolment
21/09/2016

Locations

Countries of recruitment
United Kingdom

England

Denmark

Germany

India

Israel

Italy

Netherlands

United States of America

Study participating centre
Hadassah Medical Center
Kiryat Hadassah, POB 12000
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Sponsor information

Organisation
Smart Medical Systems Ltd

ROR
https://ror.org/01w50vm31

Funder(s)

Funder type
Industry

Funder Name

Smart Medical Systems Ltd (Israel)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Adva Yoselzon.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	10/04/2019	Yes	No
Protocol file	version V1	09/07/2013	08/01/2018	No	No