

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

Submission date 17/12/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 14/01/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/04/2019	Condition category Cancer	☐ 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 colonoscope. 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

Contact name
Mr Ralf Kiesslich

Contact details
Ludwig-Erhard- Straße 100
Wiesbaden
Germany
65199

Type(s)
Public

Contact name
Mrs Adva Yoselzon

Contact details
5 HaNofar St.
Ra'anana
Israel
4366404

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)

Landesarzlekkammer 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 months) 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
Jerusalem
Israel
91120

Study participating centre
HSK, Dr. Horst Schmidt Kliniken GmbH
Ludwig-Erhard- Straße 100
Wiesbaden
Germany
65199

Study participating centre
Russells Hall Hospital
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Copenhagen University Hospital Herlev
Herlev Ringvej 75
Herlev
Denmark
2730

Study participating centre
Laniado Hospital
Kiryat Sanz
Netanya
Israel
42150

Study participating centre
Universitätsklinikum Tübingen
Otfried-Müller-Str. 10
Tübingen
Germany
D-72076

Study participating centre
San Raffaele Hospital - Milan
via Olgettina 60
Milano
Italy
20132

Study participating centre
Maastricht University Medical Centre
Postbox 5800
Maastricht
Netherlands
6202 AZ

Study participating centre
Assaf Harofe
Tzrifin
Tzrifin
Israel
70300

Study participating centre
Asian Institute of Gastroenterology
6-3-661, Somajiguda
Hyderabad
India
500 082

Study participating centre
NYU Langone Medical Center
333 E 38th St
New York
United States of America
10016

Study participating centre
Universitätsmedizin Johannes Gutenberg University Mainz
Langenbeckstraße 1
Mainz

Germany
55131

Study participating centre
Beth Israel Deaconess Medical Center
Harvard Medical School
330 Brookline Ave
Boston
United States of America
02215

Study participating centre
UMC Radboud
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525

Study participating centre
Birmingham City University
Birmingham
United Kingdom
B4 7BD

Sponsor information

Organisation
Smart Medical Systems Ltd

ROR
<https://ror.org/01w50vm31>

Funder(s)

Funder type
Industry

Funder Name

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 Yosefzon.

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