ISRCTN11821044 https://doi.org/10.1186/ISRCTN11821044

The ADENOMA study - a study of a device to improve detection of polyps during colonoscopy

Submission date 27/08/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/10/2014	**Overall study status** Completed	
Last Edited 21/05/2021	**Condition category** Digestive System	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-device-that-may-help-to-find-polyps-in-the-bowel-the-adenoma-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02552017

Secondary identifying numbers
v 5.0, 07.08.2014

Study information

Scientific Title
Accuracy of Detection using ENdocuff Optimisation of Mucosal Abnormalities

Acronym
ADENOMA

Study objectives
It is predicted that using the Endocuff Vision will improve the adenoma detection rate.

Primary objective:
1. To detect a difference in adenoma detection rate between Endocuff-Assisted Colonoscopy (EAC) and Standard Colonoscopy (SC)

Secondary objectives:
1. To detect a difference in mean adenomas detected per procedure (MAP2) between EAC and SC
2. To establish the rate of cuff exchange (that is, how often the cuff has to be removed)
3. To demonstrate non-inferiority of caecal intubation rates and insertion time to caecum between EAC and SC
4. To demonstrate non-inferiority in complete withdrawal time in procedures where no polyps are detected between EAC and SC
5. To demonstrate non-inferiority of patient satisfaction with EAC compared to SC
6. To identify any difference in future colonoscopic workload produced by increased ADR in terms of number of potential follow-up procedures based on BSG adenoma surveillance guidelines between the EAC and SC groups

These outcomes will be analysed on an intention-to-treat basis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - York. REC, ref. 14/NE/1111 - review date 12/09/2014

Study design
Multicentre prospective randomised controlled interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Conditions requiring colonoscopy assessment, colonic adenomas

Interventions
Two study arms:
1. Control arm - routine colonoscopy performed in standard fashion with no Endocuff Vision attached to scope
2. Intervention arm - colonoscopy performed with Endocuff Vision device attached to end of colonoscope
Intervention will be for the duration of the colonoscopy only. Participants will also complete a patient experience questionnaire immediately after, and within a week after, the procedure. Histology results of any polyps detected will be reviewed by the research team, and 30-day adverse events recorded.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Adenoma detection rate (ADR)

Secondary outcome measures
1. Mean adenomas detected per procedure (MAP)
2. The rate of cuff exchange (that is, how often the cuff has to be removed)
3. Caecal intubation rates and insertion time to terminal ileum (to demonstrate non-inferiority)
4. Complete withdrawal time in procedures where no polyps are detected (to demonstrate non-inferiority)
5. Patient satisfaction
6. To identify any difference in future colonoscopic workload produced by increased adenoma detection rate in terms of number of potential follow-up procedures based on BSG adenoma surveillance guidelines between the EAC and SC groups

Overall study start date
06/10/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Referral for screening, surveillance or diagnostic colonoscopy
3. Ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1772 participants (886 in each arm of the study)

Key exclusion criteria
1. Absolute contraindications to colonoscopy
2. Established or suspicion of large bowel obstruction or pseudo-obstruction
3. Known colon cancer or polyposis syndromes
4. Known colonic strictures
5. Known severe diverticular segment (that would be likely to prevent passage of the colonoscope)
6. Patients with acute colitis (ulcerative, Crohns and diverticulitis)
7. Patients lacking capacity to give informed consent
8. Pregnancy

Date of first enrolment
06/10/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tyneside Hospital
South Shields
United Kingdom
NE34 0PL

Sponsor information

Organisation
South Tyneside NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/044j2cm68

Funder(s)

Funder type
Industry

Funder Name
ARC Medical Design Ltd (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	results			No	Yes

Results article	01/02/2019		Yes	No
HRA research summary		28/06/2023	No	No