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Does using Endocuff Vision device increase the ability to find bowel polyps in bowel cancer screening endoscopy?

Submission date 12/06/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/06/2017	**Overall study status** Completed	
Last Edited 11/01/2023	**Condition category** Digestive System	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-device-that-may-help-find-manage-polyps-bowel-during-cancer-screening-test-b-adenoma

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
33224

Study information

Scientific Title

The B-ADENOMA Study: Bowel Scope - Accuracy of Detection using ENdocuff Optimisation of Mucosal Abnormalities

Acronym
B-ADENOMA

Study objectives
The aim of this study is to evaluate the effectiveness of using Endocuff Vision in detecting colonic adenomas (polyps in the bowel which may progress to bowel cancer), making sure the procedure is the same or better than the current procedure in all other aspects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee - Solihull, 20/01/2017, ref: 16/WM/0514

Study design
Randomised; Interventional; Design type: Screening, Diagnosis, Prevention, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Gastroenterology, Primary sub-specialty: Gastroenterology; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs, Oral and Gastrointestinal/ Other diseases of the digestive system

Interventions
Participants undergo a endoscopy as per usual practice. Participants are randomly allocated to one of the groups using randomisation software, stratifying for age group and gender.

Treatment arm: Participants in this arm have the Endocuff Vision mounted on the endoscope for the one-off flexible sigmoidoscopy.

Control arm: The one-off flexible sigmoidoscopy is completed as normal, without the Endocuff Vision on the scope.

Participants are followed up for 14 days after the test test to ensure there are no adverse events.

Intervention Type
Other

Primary outcome(s)
Adenoma detection rate (ADR) is measured by histological examination of polyps, recorded 14 days after the procedure

Key secondary outcome(s))
1. Mean adenomas detected per procedure are measured by histological examination of polyps, at 14 days after the procedure
2. Rate of cuff exchange (that is, how often the cuff has to be removed) at the time of the procedure
3. Complete withdrawal time in procedures where no polyps are detected, measured using withdrawal times at the time of the procedure
4. Overall procedure time is measured at time of procedure
5. ADR accounting for patient procedure based variables (e.g. accounting for extent of examination and bowel preparation), recorded at the time of the procedure
6. Rate of discovered cancers is measured by histological examination of biopsies/polyps, recorded up to 14 days after the procedure
7. Examination extent is measured using anatomical assessment of and distance (in centimetres) of intubation at the time of the procedure
8. Patient satisfaction is measured using the modified Gloucester scale of assessment of patient comfort at day of procedure and 24 hours after
9. Differences in future colonoscopic workload produced by increased ADR is measured using the change in the number of patients referred for full colonoscopy at day of the procedure
10. Changes in ADR to assess any learning curve effect is measured using primary outcome data for the first and last 20% of cases per individual colonoscopist after recruitment has completed
11. ADR of each colonoscopist prior to trial recruitment compared with their individual ADR in patients where EndocuffTM Vision was not used is measured using data from the Bowel Cancer Screening programme collected pre-trial and after the trial has completed recruitment from primary outcome data

Completion date
30/08/2018

Eligibility

Key inclusion criteria
1. Age 55 to 61 years (both male and female)
2. Referral for screening flexible sigmoidoscopy
3. Ability to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
3222

Key exclusion criteria
1. Absolute contraindications to flexible sigmoidoscopy
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 is likely to impede sigmoidoscope passage)
6. Patients with active colitis (ulcerative colitis, Crohn's colitis, diverticulitis, infective colitis)
7. Patients lacking capacity to give informed consent
8. Patients who are on clopidogrel, warfarin, or other new generation anticoagulants who have not stopped this for the procedure
9. Pregnancy

Date of first enrolment
14/02/2017

Date of final enrolment
13/02/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Tyneside District Hospital (Lead Centre)
Harton Lane
Tyne and Wear
South Shields
United Kingdom
NE34 0PL

Study participating centre
St. Mark's Hospital
Watford Road
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United Kingdom
HA1 3UJ

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road

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PO6 3LY

Study participating centre
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Stockton-on-Tees
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Study participating centre
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Bishop Auckland
United Kingdom
DL14 6AD

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North Tyneside General Hospital
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NE29 8NH

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Queen Elizabeth Avenue
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NE9 6SX

Study participating centre
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Herries Road
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S5 7AU

Study participating centre
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
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GL1 3NN

Study participating centre
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Kettering General Hospital
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N19 5NF

Study participating centre
John Radcliffe Hospital
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University College Hospital
235 Euston Road
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Study participating centre
Charing Cross Hospital
Fulham Palace Road
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W6 8RF

Study participating centre
Royal Lancaster Infirmary
Ashton Road
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Study participating centre
Addenbrooke's Hospital
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Cambridge
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CB2 0QQ

Study participating centre
Dorset County Hospital
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Study participating centre
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Sponsor information

Organisation
South Tyneside District Hospital

ROR
https://ror.org/00q75av54

Funder(s)

Funder type
Government

Funder Name
Arc Medical Design Limited

Funder Name
Norgine Limited

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to no specific patient consent being given for this.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	26/11/2020	Yes	No
HRA research summary			28/06/2023	No	No