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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
17/03/2016

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 3222; UK Sample Size: 3222

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
England

United Kingdom

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
Middlesex
United Kingdom
HA1 3UJ

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
United Kingdom
PO6 3LY

Study participating centre
University Hospital North Tees
Hardwick Road
Hardwick
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre
Bishop Auckland Hospital
Cockton Hill Road
Bishop Auckland
United Kingdom
DL14 6AD

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
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
United Kingdom
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
Rothwell Road
Kettering
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N19 5NF

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
University College Hospital
235 Euston Road
Bloomsbury
London
United Kingdom
NW1 2BU

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
Royal Lancaster Infirmary
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Dorset County Hospital
Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Watford General Hospital
Vicarage Road
Watford
United Kingdom
WD18 0HB

Sponsor information

Organisation
South Tyneside District Hospital

Sponsor details
South Tyneside NHS Foundation Trust
Harton Lane
South Shields
England
United Kingdom
NE34 0PL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q75av54

Funder(s)

Funder type
Government

Funder Name
Arc Medical Design Limited

Funder Name
Norgine Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal by October 2019. International presentation at UEGW and BSG annual meetings. Presentation to BSG Endoscopy Research Committee and BCSP

Intention to publish date
31/12/2018

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