

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

<b>Submission date</b> 12/06/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Mr Martin Walls

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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 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 Endocuff<sup>TM</sup> 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  
United Kingdom  
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?
<a href="#">Results article</a>	results	01/11/2020	26/11/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No