

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

<b>Submission date</b> 27/08/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/05/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT02552017

### Protocol serial number

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

## **Study type(s)**

Diagnostic

## **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(s)**

Adenoma detection rate (ADR)

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**South Tyneside Hospital**

South Shields

United Kingdom

NE34 0PL

## Sponsor information

**Organisation**

South Tyneside NHS Foundation Trust (UK)

**ROR**

<https://ror.org/044j2cm68>

## Funder(s)

**Funder type**

Industry

**Funder Name**

ARC Medical Design Ltd (UK)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/02/2019		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>				No	Yes