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# Does the new disposable distal attachment (Endocuff) improve detection of pre cancerous polyps?

**Submission date**
04/07/2017

**Recruitment status**
No longer recruiting

**Registration date**
12/07/2017

**Overall study status**
Completed

**Last Edited**
30/11/2021

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
In the UK, around 1 in 16 men and 1 in 20 women will develop bowel cancer at some point in their lives. Most bowel cancers happen when a type of polyp (fleshy growth on the lining of the bowel) called an adenoma becomes cancerous. Doctors use a camera, known as a colonoscope, to see the inside of the large bowel to find and remove the polyps if necessary. Removing pre-cancerous polyps is known to reduce the chances of a person developing bowel cancer in the future. A new device, called the Endocuff Vision, which is attached to the end of the colonoscope, has been shown to improve the rate of polyp detection at colonoscopy. It is a small plastic device which helps by holding the folds of the bowel back to give a clear view of the inside of the bowel. Before the arrival of Endocuff a similar device called Cap has been in use to improve the detection and management of adenomas. The main drawback of the cap is the limited view of the bowel lining when it is attached to the tip of the colonoscope. The aim of this study is to find out if using the Endocuff Vision helps colonoscopists to find polyps which are hiding behind the folds. The study also assesses whether procedures performed using the Endocuff Vision are longer or more uncomfortable for the patient than colonoscopies performed with Cap.

Who can participate?
Adults over the age of 18 undergoing a colonoscopy

What does the study involve?
Each patient undergoes two colonoscopies with the Cap and Endocuff by the same endoscopist in a random order. After the first procedure, the cap or cuff is removed or fitted to the tip of colonoscope, and the second procedure begins immediately. Any polyps detected and removed are followed up. Patients remain in the study for 30 days to record any complications and side effects. There are no additional follow-up visits needed for this. The timing of outpatient appointments and results are not affected by the study and are as standard.

What are the possible benefits and risks of participating?
It is known that finding pre-cancerous polyps and removing them reduces the risk of bowel

cancer. If this study shows that using the Endocuff Vision helps colonoscopists to find more polyps, the risk of bowel cancer in these patients is reduced when compared to the use of a cap. If these polyps are found to be pre-cancerous when they are looked at in the laboratory, the doctors' team make sure participants receive the best treatment and follow up. On the other hand, the study may not benefit participants at this time, but the information from this study may help others who have polyps. Attaching the Endocuff Vision or cap to the end of the colonoscope slightly increases the width of the camera. This may make inserting the camera through the anus slightly more uncomfortable for a few seconds. There is a very small possibility that the Endocuff Vision or Cap becomes dislodged during the procedure. In this situation the colonoscopist removes the Endocuff or Cap using a net or graspers. The Endocuff Vision may cause very minor grazes to the bowel wall.

Where is the study run from?
London North West Hospitals NHS Trust - St Mark's Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to November 2017

Who is funding the study?
London North West Healthcare NHS Trust (UK)

Who is the main contact?
1. Dr Rajaratnam Rameshshanker
2. Dr Zacharias P. Tsiamoulos
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# Contact information

### Type(s)
Scientific


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# Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
Version 6

# Study information

**Scientific Title**
Is EndocuffTM Vision assisted colonoscopy superior to Cap assisted colonoscopy to detect adenomas?

**Acronym**
DETECT

**Study objectives**
The hypothesis is that Endocuff improves polyp detection when compared to Cap, and that it would improve polyp detection rate by 10%.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
East of England - Cambridge East Research Ethics Committee, 04/01/2016, ref: 15/EE/0415

**Study design**
Prospective randomised back to back 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
Colonic polyps detection

### Interventions
This is a back to back study to compare the Cap and Endocuff to detect polyps during colonoscopy. Each patient will undergo two consecutive colonoscopies by the same endoscopist in a randomised order (computer generated randomisation sequence). After the procedure, the cap or cuff will be removed or fitted to the tip of colonoscope, and the second procedure will begin immediately. Intra-procedure data will be collected by the research team onto a case report form (CRF). Any polyps detected and removed will be followed up, and histological diagnosis recorded post procedure by the research team. All colonoscopies will be calibrated and serviced according to British Society Gastroenterology guidelines. Patients will remain in the study for 30 days to allow collection of standard post-colonoscopy complication data through review of medical notes after the 30 day period has elapsed. Serious Adverse Events (SAEs) will also be recorded for all patients from the time of colonoscopy to 30 days post-procedure. There will no additional follow-up visit needed as a result of this. The timing of out-patient appointments and results will not be affected by the study and will be as standard for each unit. Data will be collated and analysed by the research team by 31/08/2017.

### Intervention Type
Device

### Primary outcome measure
1. Polyp miss rate, calculated at the end of the study period
2. Adenoma miss rate, calculated at the end of the study period

### Secondary outcome measures
1. Caecal intubation time and withdrawal time, collected using case report form at baseline
2. Discomfort during the procedure, measured using standard scoring system used routinely in endoscopy units on a 5-point discomfort scale, collected at baseline
3. Removal rate of cap and Endocuff, collected using case report form at baseline

### Overall study start date
01/11/2015

### Completion date
30/11/2017

## Eligibility

### Key inclusion criteria
Adults over the age of 18 years undergoing a colonoscopy

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
154

### 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 is likely to impede colonoscope passage)
6. Patients with active colitis (ulcerative colitis, Crohn’s colitis, diverticulitis, infective colitis)
7. Patients lacking capacity to give informed consent
8. Pregnancy
9. Patients who are on clopidogrel, warfarin, or other new generation anticoagulants /antiplatelets who have not stopped this for the procedure.

### Date of first enrolment
15/04/2016

### Date of final enrolment
31/08/2017

## Locations

### Countries of recruitment
United Kingdom

### Study participating centre
**London North West Hospitals NHS Trust - St Mark's Hospital**
Harrow
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# Sponsor information

### Organisation
London North West Healthcare NHS Trust

### Sponsor details
Watford Road
Harrow
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England
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/04cntmc13

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
London North West Healthcare NHS Trust

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
30/11/2018

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rajaratnam Rameshshanker.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 08/06/2018 | 30/11/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |