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Is a camera in a capsule as accurate as a colonoscopy at diagnosing bowel disease?

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Registration date 23/10/2024	**Overall study status** Ongoing	
Last Edited 01/10/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Colonoscopy is the current 'gold standard' method of diagnosing bowel disease. Here, a long, thin, flexible telescope is inserted, from the bottom, through the bowel by a trained healthcare worker. It is an uncomfortable procedure. Many patients need to be given intravenous sedation and/or pain relief to be able to cope with it. In the UK, the demand for colonoscopy exceeds the NHS's capacity to provide it. As a result, the diagnosis of a serious disease is being delayed. Colon capsule is a new technology that may be able to provide additional NHS capacity. It may also be better tolerated by some patients. The capsule is a camera in a pill that is swallowed, and which passes safely and usually painlessly through the bowel, taking pictures. It is the size of a large tablet, about 3cm long and 1cm wide, rounded at both ends with a smooth plastic casing. This makes it easy to swallow. It has a camera at each end to capture images of the bowel and a battery life of 10 hours. On average, after about 5 hours the capsule passes out naturally. It is disposable and can be flushed away safely down the toilet. A recorder needs to be worn around the waist to receive the capsule images. Later these are processed to create a report. As with colonoscopy, the bowel needs to be clean for the capsule test. This means that the day before either procedure, the patient will not be able to eat food, but will take clear fluids and purging laxatives. Many people find this the most difficult part of having a colonoscopy or capsule. On the day of the capsule, extra laxatives will need to be taken to help it pass through the bowel.

Who can participate?

Patients 18 years old and over due to have a colonoscopy because of suspected serious bowel disease (colitis or colorectal cancer) or for routine surveillance after polyp removal

What does the study involve?

Patients who decide to take part in the study will be asked to have a colon capsule endoscopy in addition to their colonoscopy. The colon capsule endoscopy will be booked in for the morning and the colonoscopy will be booked in the afternoon so that the capsule has had sufficient time to pass through the stomach and bowel and take pictures of the bowel. Doing both tests on the same day means that participants do not need to take the bowel preparation twice. However, participants would be asked to take some additional laxatives throughout the day called 'boosters', to help the capsule move along internally. Participants will be informed of the results of both procedures.

What are the possible benefits and risks of participating?
No diagnostic test is perfect and even though a colonoscopy is considered the best procedure available, it can miss significant bowel disease. The opportunity to have two bowel procedures may provide participants with an additional degree of certainty that nothing has been missed.

Additionally, the information collected in this study may help to improve the way people with suspected bowel disease are investigated in the future.

Whilst the bowel preparation the day before the colon capsule endoscopy is the same as that for the colonoscopy, the additional medicines, and laxatives (boosters) taken on the day of the procedure may add to the discomfort of the day, causing additional nausea, tiredness, or pain, although pain is uncommon. This is usually temporary and will go away once the procedure is complete. Some participants may find the long day tiring or difficult to cope with. It is important to drink clear fluids throughout the day to avoid dehydration and to ensure that the bowel is as clean as possible so that all areas of the bowel can be seen.

Rarely (1 in 600 cases) the capsule does not pass through the bowel and can become stuck in the bowel (retention). If this is suspected the doctor may decide that an X-ray and/or CT Scan of the abdomen is required. These examinations would be extra to those that participants would have if they did not take part. X-rays and CT scans both use ionising radiation to form images of the body and provide the doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The population are all at risk of developing cancer during their lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. If you have an x-ray, the chances of this happening to you may be increased to around 50.002%. If you have an x-ray and a CT scan, the chances of this happening to you may be increased to about 50.03%

Even if the capsule is retained in the bowel, it is unlikely to cause a blockage. Occasionally, an additional endoscopy procedure may be needed to retrieve the capsule. If this is not possible, it is most often because of an undiagnosed narrowing disease of the bowel such as a tumour or stricture and this itself will require planned surgery to deal with. A CT scan may be needed to make this diagnosis. Here the colon capsule will have identified the problem. Very rarely the capsule may cause a complete blockage of a narrowed bowel (acute obstruction). This would cause severe pain and vomiting and may require emergency surgery.

The risk of not being able to swallow the capsule is about one in a thousand and there is an extremely rare risk of the capsule going down the wrong way into the lungs rather than the stomach (aspiration).

Participants would not be able to have an MRI scan of any part of the body (for a related or unrelated reason) until there is confirmation that the capsule has passed out of the bottom.

Where is the study run from?
The study is being run by a research team from York & Scarborough Teaching Hospitals and the Centre for Healthcare Randomised Trials at the University of Aberdeen (CHaRT) and the Centre for Trials Research (CTR) at Cardiff University.

When is the study starting and how long is it expected to run for?
November 2022 to March 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR)

Who is the main contact?
Miss Monica Haritakis (Research Programme Manager), yhs-tr.colocapstudy@nhs.net

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
331349

Central Portfolio Management System (CPMS)
57318

National Institute for Health and Care Research (NIHR)
158034

Study information

Scientific Title
ColoCap: determining the diagnostic accuracy of colon capsule endoscopy compared to standard colonoscopy in patients at risk of colorectal disease

Acronym
ColoCap

Study objectives
Colon capsule endoscopy has equivalent diagnostic accuracy, in terms of sensitivity, as standard colonoscopy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2024, North East - Tyne & Wear South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048120; tyneandwearsouth.rec@hra.nhs.uk), ref: 24/NE/0178

Primary study design
Interventional

Study design
Non-randomized complex interventional and qualitative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colon capsule endoscopy diagnostic accuracy compared with as standard colonoscopy

Interventions
This study has three research workstreams (WS). In WS 1, a paired (back-to-back) study will be performed. Patients due for a colonoscopy because of suspected serious bowel disease or for routine surveillance after polyp removal will be invited to join the study. The study will be as similar to a standard colonoscopy as possible. After a day of bowel preparation, the participant will swallow the capsule under supervision, first thing in the morning and then, later that afternoon, a colonoscopy will be performed. This will allow up to 8 hours for the capsule to pass. The participant will not be able to eat during this time so it will be a long day for participants to cope with, but it will avoid the need for two lots of bowel preparation and investigations on two separate days. Up to 30 sites across the UK will be involved to ensure inclusivity. This study will allow us to compare the capsule findings with those of the direct colonoscopy and determine how accurate the capsule is at detecting bowel disease. WS2 will compare the costs of the capsule over those of a colonoscopy by undertaking an economic evaluation. WS 3 will ask participants and the clinical team what their experience of the capsule has been.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Per-patient detection of the combined endpoint of visible mucosal colorectal lesions (CRC, polyps and colitis) in participants who have had a complete and adequately prepared colon capsule endoscopy (CCE) and colonoscopy; the endpoint will include post-review colonoscopy when appropriate, on days 0-7 for per-patient reporting with interim analyses in months 12, 18, 24, 30 and 36, and final analysis between months 36-40

Key secondary outcome(s)

The following secondary outcome measures will be assessed on days 0-7 for per-patient reporting with interim analyses in months 12, 18, 24, 30 and 36, and final analysis between months 36-40:
1. Diagnostic accuracy for specific lesion types including all polyps and by size (<6mm, 6-9mm and >9mm)
2. Per-lesion matching
3. Colon capsule endoscopy (CCE) completion rates and times, bowel preparation adequacy rates, retention rates and adverse events will be recorded while for colonoscopy it will be standard performance measures and adverse events
4. CCE performance characteristics compared to colonoscopy will be assessed based on patient demographics, FIT and other disaggregated groups
5. A supplementary 'intention to investigate' comparative analysis of CCE versus colonoscopy

Further objectives will be measured as follows:
6. Intra- and inter-reader variability assessed via the identification and impact of any variability on diagnostic accuracy of CCE. A structured proforma will be developed to address this at months 28-37
7. The development of health economic models (months 17-37) assessed by evaluating the costs and benefits of CCE in relevant patient groups will be undertaken between months 38-40:
The key outputs of the symptomatic and surveillance CRC models will be:
7.1. Total incremental costs
7.2. Total incremental QALYs and life-years
7.3. Cost per colonoscopy avoided
7.4. The excess number of CRC detected
7.5. For IBD colitis a third model will be developed to capture the economic impact of using CCE within the diagnostic pathway for IBD
8. The evaluation of the patient and clinician experience of CCE will be measured using qualitative analyses to provide a thematic account, using patient and clinician experience, between months 34-39

Completion date

31/03/2027

Eligibility

Key inclusion criteria

1. Patients with suspected CRC who have had a FIT within 3 months of referral, where a new IBD Colitis is suspected or patients having a 3-yearly post-polypectomy surveillance colonoscopy
2. Patients who feel they can tolerate a same-day CCE and colonoscopy investigation or would be willing to have the colonoscopy on an alternative day
3. Patients who feel able to swallow the CCE
4. Patients who are able and willing to give informed consent to participate

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients < 18 years
2. Patients who are unable to safely swallow the CCE*
3. Patients who are unable to safely and fully comply with the bowel preparation*
4. Patients clinically at risk of stricturing bowel disease, such as Crohn's disease
5. Patients who have ever received abdominal or pelvic external beam radiotherapy
6. Patients with a history of bowel obstruction
7. Patients who have had a (partial) colectomy
8. Patients who are currently pregnant or breastfeeding
9. Symptomatic patients with suspected CRC who have not had a FIT within 3 months of referral
10. Patients with a permanent pacemaker or other implanted electromedical device
11. Patients who will not be able to safely tolerate the study*
12. Patients in whom the bowel preparation for CCE will likely be inadequate

* These exclusion criteria will require some clinical judgement in line with the existing approach to CCE and colonoscopy in clinical practice. Judgement of ability to tolerate the study requires an assessment of frailty per se, rather than a specific co-morbidity. However, it is likely to include patients with conditions such as cirrhosis, diabetes, stroke, peripheral vascular, heart or renal disease or cognitive impairment.

This exclusion criteria will also require some clinical judgement in line with the existing approach to CCE and colonoscopy in clinical practice. It will include patients with slow gastrointestinal motility, such as idiopathic slow transit constipation, those currently using opioid or tricyclic antidepressant medication, a history or prior poor bowel preparation and/or who require regular laxatives in their daily rounds.

Date of first enrolment
01/01/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Sponsor (on the advice of the TMG), in accordance with the good practice principles for sharing individual participant data from publicly funded clinical trials at the end of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/09/2025	01/10/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes