ISRCTN10451355 https://doi.org/10.1186/ISRCTN10451355

COLO-DETECT: Can an artificial intelligence device increase detection of polyps during colonoscopy?

Submission date
27/01/2021

Recruitment status
No longer recruiting

Registration date
12/02/2021

Overall study status
Completed

Last Edited
04/03/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and Study Aims
Bowel cancer (also called colorectal cancer) is common, affecting 1 in 15 men and 1 in 18 women in the UK in their lifetime. Many bowel cancers develop from polyps. These polyps are small abnormal growths from the lining of the bowel. It is possible to remove polyps and therefore prevent them from progressing to colorectal cancer. The best tool for doing this is a procedure called colonoscopy (a camera test of the large bowel). However, colonoscopy does not pick up all polyps.

Because missed polyps can develop into bowel cancer, it is important to detect and remove as many polyps as possible during a colonoscopy. Many different things have been introduced to try to improve the ability to detect polyps, the most recent of which is artificial intelligence devices. GI Genius is an artificial intelligence device in the form of a box that is connected to existing colonoscopy equipment; it analyses the video images from the camera in real time. Any areas that may represent an abnormality are then highlighted within a green box, alerting the colonoscopist (person performing the camera test) to its presence. The area in the box can then be assessed more closely by the colonoscopist to decide whether it needs to be removed or not.

The COLO-DETECT trial will assess whether colonoscopists using GI Genius to assist them are able to detect more polyps (especially a type of polyp called an adenoma) during colonoscopy than when they don't use GI Genius. It will also gather data on many other aspects of the colonoscopy (including participants' experience of the procedure) to ensure that they are not adversely affected by using the GI Genius device.

Who can participate?
Adults who have been referred for a colonoscopy because of bowel symptoms, because they have had a colonoscopy for bowel problems before and need a follow-up procedure, or as part of the National Bowel Cancer Screening Programme. There are certain reasons why it is not appropriate to take part, which will be checked with people prior to enrolling them in the study.

What does the study involve?
People who agree to participate will be randomly allocated to have either a standard colonoscopy or a colonoscopy with GI Genius turned on for the procedure. Besides the use of GI Genius, the procedure will be entirely normal for the hospital where they are having their colonoscopy. Nurses looking after patients during their colonoscopy will record some details of the procedure as it happens. After the colonoscopy, the recovery from the procedure and discharge from the hospital will be as normal.

Participants will be given 2 questionnaires and asked to complete them the following day and return them to the study research team in a pre-paid envelope. Approximately 14 days after the colonoscopy a member of the research team will call the participant to ask if they have remained well since the procedure and record any details of visits to the GP or hospital in that time that were related to the colonoscopy. The research team will also review the care records of participants to gather further information about the procedure and any polyps that were identified. There will be no further contact from the research team after this.

What are the potential benefits and risks of participating?
People participating will potentially have a greater number of pre-cancerous polyps identified and removed during their colonoscopy, which may in turn reduce the likelihood of that individual subsequently developing bowel cancer.

There are not thought to be any risks resulting directly from the use of GI Genius, but if it does detect more polyps that are then removed then there is a small increase in the risk of complications such as bleeding or perforation (a small hole in the bowel) from the larger number of polyp removals. Bleeding or perforation may or may not require additional tests or treatment.

Where is the study run from?
South Tyneside and Sunderland NHS Foundation Trust (UK) in partnership with Newcastle University (UK). 8 hospital trusts across England, who will be inviting people to participate.

When is the study starting and how long is it expected to run for?
From March 2020 to May 2023

Who is funding the study?
Medtronic (Ireland) and the National Institute for Health Research (UK)

Who is the main contact?
Alexander Seager
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04723758

Integrated Research Application System (IRAS)
286426

Central Portfolio Management System (CPMS)
48022

Study information

Scientific Title
COLO-DETECT: A randomised controlled trial of lesion detection at colonoscopy using the GI Genius™ artificial intelligence platform

Acronym
COLO-DETECT

Study objectives
There is no difference in the number of adenomas detected per colonoscopy when colonoscopy is assisted by the GI Genius Artificial Intelligence Device compared to standard colonoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, West of Scotland REC 4 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 21-WS-0003

Primary study design
Interventional

Study design
Multicentre two-arm interventional randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Adenoma of the colon, adenoma of the rectum, colorectal polyps, colorectal cancer

Interventions
Current intervention as of 26/07/2021:
Immediately prior to colonoscopy, recruited participants will be randomised (1:1) to either GI Genius-Assisted Colonoscopy (GGC) or Standard Colonoscopy (SC) using a secure web-based randomisation platform. The colonoscopy will then completed as per standard practice for the unit where the colonoscopy is performed, and procedural data will be collected. 14-days post-procedure, participant health records (including case notes and histology records) and endoscopy reports will be reviewed, to gather post-procedural data including the nature of polyps identified and removed, and participants will be contacted by telephone to capture the occurrence of any post-procedural adverse events. Participants will also be asked to complete validated patient-reported experience measures and health-related quality of life questionnaires the following day and return these to the study team by post in a pre-paid envelope.

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Previous intervention:
Immediately prior to colonoscopy, recruited participants will be randomised (1:1) to either GI Genius-Assisted Colonoscopy (GGC) or Standard Colonoscopy (SC) using a secure web-based randomisation platform. The colonoscopy will then completed as per standard practice for the unit where the colonoscopy is performed, and procedural data will be collected. 14-days post-procedure, participant health records (including case notes and histology records) and endoscopy reports will be reviewed, and participants will be contacted by telephone to gather post-procedural data including the nature of polyps identified and removed, and occurrence of any post-procedural adverse events. Participants will also be asked to complete validated

patient-reported experience measures and health-related quality of life questionnaires the following day and return these to the study team by post in a pre-paid envelope.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. Mean Adenomas per Procedure (MAP), the average number of adenomas detected per colonoscopy, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure

Key secondary outcome(s)
1. Adenoma Detection Rate (ADR), the proportion of colonoscopies in which one or more adenomas was detected, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
2. MAP in the 'screening' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
3. MAP in the 'symptomatic' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
4. ADR in the 'screening' participant population in whom at least one adenoma is detected at colonoscopy, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
5. ADR in the 'symptomatic' participant population in whom at least one adenoma is detected at colonoscopy, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
6. Mean number of Polyps per Procedure (MPP), number of polyps per procedure detected at colonoscopy, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
7. MPP in the 'screening' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
8. MPP in the 'symptomatic' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
9. Polyp Detection Rate (PDR), the proportion of participants in whom at least one polyp is detected at colonoscopy, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
10. PDR in the 'screening' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
11. PDR in the 'symptomatic' participant population, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
12. Polyp location, size, morphology, and histology (if retrieved), measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
13. Sessile Serrated Polyp (SSP) detection rate, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
14. Colorectal Cancer (CRC) detection rate, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure

15. Advanced Adenoma (AA) detection rate, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
16. Caecal Intubation Rate, the proportion of colonoscopies in which the colonoscope reaches the furthest extent of the colon, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
17. Insertion time to caecum, the time taken to reach the furthest point of the large bowel, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
18. Total Procedure Time, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
19. Total Withdrawal Time, the time taken to remove the colonoscope from the furthest point of the colon in the absence of any polyps, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
20. Colonoscopist-assessed patient comfort score, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
21. Nurse-assessed patient comfort score, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
22. Patient-reported experience measured using a validated Patient-Reported Experience Measure (Newcastle ENDOPREM) at 1 day post-procedure
23. Patient-reported health-related quality of life measured using the EuroQoL EQ-5D-5L quality of life questionnaire at 1 day post-procedure
24. Projected future endoscopy workload, the need for further colonoscopy for each participant, according to national guidelines on polyp surveillance from procedural data, determined by the findings at the index colonoscopy, participant health records, and endoscopy reports collected at 14 days post-procedure
25. MAP according to the National Bowel Cancer Screening Programme (BCSP) status of colonoscopist, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
26. ADR according to BCSP status of colonoscopist, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
27. Change in the number of adenomas detected per colonoscopy, for each colonoscopist, over the course of the study, calculated as the MAP for the first 20% and the last 20% of participants chronologically for each colonoscopist, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
28. Change in the proportion of participants in whom at least one adenoma is detected during colonoscopy, for each colonoscopist, over the course of the study, calculated as the ADR for the first 20% and the last 20% of participants chronologically for each colonoscopist, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
29. MAP for each participating colonoscopist, from pre-study to intra-study for the Standard Colonoscopy (SC) arm only, to assess for a contamination or learning effect, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
30. ADR for each participating colonoscopist, from pre-study to intra-study for the SC arm only, to assess for a contamination or learning effect, measured from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
31. Cost-effectiveness of GI Genius-Assisted Colonoscopy (GGC) versus SC, the cost of equipment, staff, histology, unplanned admission, and other related costs will be calculated from procedural data, participant health records, and endoscopy reports collected at 14 days post-procedure
32. MAP amongst colonoscopists not participating in the study, over the duration of the study, measured from data reported by endoscopy units as part of the normal endoscopy quality

assurance programme collected at 14 days post-procedure
33. ADR amongst colonoscopists not participating in the study, over the duration of the study, measured from data reported by endoscopy units as part of the normal endoscopy quality assurance programme collected at 14 days post-procedure

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Capacity to provide informed consent
3. Referred for a diagnostic colonoscopy which is due to be performed by a colonoscopist who is able to perform GI Genius-assisted colonoscopy as part of the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
2032

Key exclusion criteria
1. ≥1 absolute contraindications to colonoscopy
2. Lacking capacity to give informed consent
3. Confirmed or expected pregnancy
4. Established or suspected large bowel obstruction or pseudo-obstruction
5. Known presence of colorectal cancer or polyposis syndromes
6. Known colonic strictures (meaning that the colonoscopy may be incomplete)
7. Known active colitis (ulcerative colitis, Crohn's colitis, diverticulitis, infective colitis)
8. Inflammatory Bowel Disease (IBD) surveillance procedures
9. On antiplatelet agents or anticoagulants and have not stopped this for the procedure (as polyps cannot be removed and thus histology cannot be confirmed)
10. Attending for a planned therapeutic procedure or assessment of a known lesion
11. Referred with polyps identified on Bowel Scope procedure (Bowel Scope is a UK screening programme where all adults aged 55 are offered a one-off flexible sigmoidoscopy)

Date of first enrolment

29/03/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Tyneside District Hospital
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Study participating centre
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Sponsor information

Organisation
South Tyneside NHS Foundation Trust

ROR
https://ror.org/044j2cm68

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2024	04/03/2025	Yes	No
Protocol article		09/06/2022	10/06/2022	Yes	No
Participant information sheet	version V1.2	25/01/2021	12/02/2021	No	Yes
Participant information sheet	version v2.0	27/04/2021	26/07/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes