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Colorectal cancer cohort study (COLO-COHORT)

Submission date 11/07/2019	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 23/12/2019	**Overall study status** Ongoing	
Last Edited 25/04/2025	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.colospeed.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04185779

Secondary identifying numbers
Nil known

Study information

Scientific Title
Colorectal Cancer Cohort Study (COLO-COHORT)

Acronym
COLO-COHORT

Study objectives
1. It is possible to identify factors (derived from socio-demographics, medical history, family history, lifestyle, FIT test results, blood test results) which successfully predict risk of colorectal neoplasia in individuals with symptoms attending for colonoscopy
2. It is possible to identify those individuals most likely to have advanced adenomas (adenomas ≥10mm, any villous component, presence of high-grade dysplasia) or CRC at surveillance colonoscopy
3. Individuals with and without colorectal neoplasia have distinct microbiome profiles
4. To develop a platform of patients who consent to future contact for future research studies (COLO-SPEED)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/06/2019, West Midlands - Edgbaston Research Ethics Committee (Royal College of Surgeons Edinburgh, Birmingham B3 2BB; 02071048036; NRESCommittee.WestMidlands-Edgbaston@nhs.net), ref: 19/WM/0193

Study design
Observational multicentre cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Colorectal neoplasia, colorectal cancer

Interventions
Group A (cross-sectional arm, 10,000 patients)
In 6,000 patients from this group, patients will be asked to submit a Faecal Immunochemical Test (FIT) sample and be asked to have blood tests taken including blood for DNA extraction. In the remaining patients, we will record recent blood results of interest. For all patients, we will obtain information on their past medical history, alcohol history, smoking history, family history, anthropometric measurements including waist circumference, and information from their colonoscopy and histology of polyps removed or biopsies taken.

COLO-SPEED, Group B:
Patients will be asked to consent to future contact for collection of additional information, contact for future research studies, use of samples or information from this study to be used in future research studies, for longitudinal follow up through medical notes or national databases, and use of information from previous lower gastrointestinal endoscopy and histology as well as laboratory results in future research studies.

Follow up for patients who consent for long term follow up will be 10 years post consent.

Intervention Type
Other

Primary outcome measure
The occurrence of colorectal neoplasia (colorectal cancer and advanced adenomas), measured by reviewing patient endoscopy reports, blood results, and health questionnaire. These will be analysed via logistic regression and subsequent structural equation modelling. Timepoint: baseline

Secondary outcome measures
Stool microbiome in different patient subgroups (i.e., normal colon, adenomas, bowel cancer), measured by reviewing stool samples at baseline

Overall study start date
01/10/2018

Completion date
14/01/2026

Eligibility

Key inclusion criteria
Group A:
1. Aged ≥30 years and able to give informed consent
2. Patients attending colonoscopy:
2.1 Through Bowel Cancer Screening Programme (FIT positive, Bowelscope conversion, surveillance)

2.2 Through standard NHS care (most commonly due to iron deficiency anaemia, altered bowel habit, weight loss, rectal bleeding, planned polypectomy, those referred on basis of family history, abnormal cross-sectional imaging, polyp surveillance or post CRC surveillance)

(COLO-SPEED) Group B:
1. Any patient attending for colonoscopy and able to give informed consent
2. At least 18 years old
3. In a centre supported by COLO-SPEED infrastructure (i.e. in North of England)

Participant type(s)
Patient

Age group
Adult

Lower age limit
30 Years

Sex
Both

Target number of participants
15,000

Key exclusion criteria
Group A:
1. Unable to give informed consent
2. Known polyposis syndrome
3. Previous total colectomy
4. Known colonic stricture which would limit complete colonoscopy
5. Attending for planned therapeutic procedure other than polypectomy, such as insertion of colonic stent
6. Attending for assessment of known inflammatory bowel disease (IBD) activity or for IBD surveillance
7. Patients currently recruited into an interventional CTIMP for CRC prevention

COLO-SPEED (Group B):
1. DOes not meet inclusion criteria

Date of first enrolment
01/08/2019

Date of final enrolment
14/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tyneside District Hospital
Harton Lane
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NE34 0PL

Sponsor information

Organisation
South Tyneside and Sunderland NHS Foundation Trust

Sponsor details
South Tyneside District Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/044j2cm68

Funder(s)

Funder type
Charity

Funder Name
Guts UK Charity

Alternative Name(s)
Guts UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
For academic and clinical dissemination, the results will be submitted for publication in high-impact international peer-reviewed journals and presented to scientific meetings.
For dissemination to patients and public, lay summaries will be prepared, posted on the study website, and further disseminated through the websites of the individual participating sites and charities.
In order to contribute to a significant beneficial impact on clinical practice, the risk model will need to be tested for effectiveness compared to standard clinical pathways in independent cohorts in the UK and abroad. In conjunction with COLO-SPEED the research team are collaborating closely with UK and international clinical and research networks and organisations including British Society of Gastroenterology, Association of Coloproctology GBI, UK Therapeutic Cancer Prevention Network, Netherland society of Gastroenterology and the European Society of GI Endoscopy. COLO-SPEED is also supported by NHS England, Public Health England, NHS BCSP, Scottish Cancer Taskforce, Northern Ireland Cancer Network, Scottish Cancer Prevention Network and the Wales Cancer lead. The collaboration of these professional, research and governmental organisations will ensure that the risk model developed by COLO-COHORT will be tested and implemented in a manner that has maximal impact upon clinical care.

Intention to publish date
14/01/2027

Individual participant data (IPD) sharing plan
The study management group will develop guidelines and processes at which other researchers can access this data, and this will be subject to review and approval from the study management group and PPI representatives. The guidelines and process to this will be made available on the study website (colospeed.org which is being developed). Patients will have been able to consent to use of their information in future research studies, as such only data from those who have consented to this will be made available. The timelines at which the data will be available and for how long will be disclosed at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No