# Colorectal cancer cohort study (COLO-COHORT)

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

## Plain English summary of protocol

Not provided at time of registration

#### Study website

https://www.colospeed.org

# Contact information

## Type(s)

Scientific

#### Contact name

Mrs Amy Burns

#### Contact details

Research and Innovation Department Old Child and Family Block South Tyneside District Hospital Harton Lane South Shields United Kingdom NE34 0PL +44 (0)191 404 1000 ext 2237 amy.burns6@nhs.net

# 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 South Shields United Kingdom NE34 0PL

# Sponsor information

## Organisation

South Tyneside and Sunderland NHS Foundation Trust

#### Sponsor details

South Tyneside District Hospital South Shields England United Kingdom NE34 0PL +44 (0)191 4028194 claire.livingstone5@nhs.net

#### 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