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Testing a new microchip system to detect bowel cancer markers in blood and stool samples

Submission date
16/10/2025

Recruitment status
Not yet recruiting

Registration date
02/11/2025

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Colorectal cancer is the second leading cause of cancer deaths globally. Colorectal cancer mortality and morbidity can be reduced and patient prognosis improved if cases are detected and treated early and with personalised patient care guided by genetic profiling. The symptoms of colorectal cancer poorly predict the likelihood of cancer. Current non-invasive stool tests are not accurate. A negative stool test does not always exclude colorectal cancer, and false-negative tests cause false reassurance, resulting in the patient not receiving life-saving treatment. The high false-positive rates of current screening stool tests result in many patients undergoing unnecessary invasive tests, such as colonoscopy and CT colonography, which are limited by the requirement for bowel preparation, patient acceptance, patient compliance, patient anxiety and discomfort, risk of complications, endoscopy and radiology service capacities, and higher costs. Colorectal cancer cells release DNA fragments into the blood and stools. Analysis of tumour DNA in blood or stool samples, so-called liquid biopsy, can detect colorectal cancer at an early stage and serve as a diagnostic, prognostic, and monitoring tool, and can guide personalised treatment. A liquid biopsy has the potential to detect tumour-specific genetic signatures and to reflect the total tumour burden; it is non-invasive and can be collected repeatedly with minimal discomfort to the patient. Current tumour DNA detection techniques are yet to be integrated into clinical use because they are laboratory-based, time-consuming, and expensive. The overall aim is to develop an innovative, non-invasive, easy-to-use, point-of-care microchip-based test that will allow the simultaneous detection of multiple tumour-specific genetic markers for colorectal cancer in blood and stools, to guide therapy and serve as a diagnostic, prognostic, and monitoring tool. This pilot study aims to assess the ability of this microchip-based system to detect genetic biomarkers of colorectal cancer in stool and blood samples.

Who can participate?
Adult patients diagnosed with any stage of colorectal cancer.

What does the study involve?
Patients diagnosed with colorectal cancer based on histology will be recruited to this pilot study. Only members of the patient's existing clinical care team will have access to patient records

without explicit consent to identify potential participants, check whether they meet the inclusion criteria or make the initial approach to patients to enquire if they are interested to learn more information about the study. If potential participants express an interest to learn more about the study, they will be contacted by the research team and will be provided with relevant information about the study.

Participants in the trial will be asked if they can provide a sample of their blood and stool. DNA will be extracted from the blood and stool samples and tested with the microchip device to assess the ability of the microchip to detect genetic (DNA) markers linked to colorectal cancer. After testing with the microchip, all samples will be discarded.

What are the possible benefits and risks of participating?
There is no actual research intervention, and therefore, there are no specific benefits for research participants apart from the benefit of taking part in research. No significant risk of harm is anticipated to the patients participating in the study.

Where is the study run from?
The participants will be recruited from the Cambridge University Hospitals NHS Foundation Trust, UK. The microchip testing will be performed at the scientific laboratories at Imperial College London, UK.

When is the study starting and how long is it expected to run for?
October 2025 to September 2026

Who is funding the study?
1. The joint Red Trousers Day - Penguins Against Cancer: Simon Bunting Research Award, UK
2. The National Institute for Health and Care Research (NIHR) Cambridge Biomedical Research Centre, UK

Who is the main contact?
Dr Constantinos Simillis, c.simillis@nhs.net

Plain English summary under review with external organisation

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Constantinos Simillis

ORCID ID
https://orcid.org/0000-0001-8864-4350

Contact details
Cambridge Colorectal Unit, Addenbrookes Hospital, Hills Road
Cambridge
United Kingdom

CB2 0QQ
+44 (0)1223805000
c.simillis@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291551

ClinicalTrials.gov (NCT)
Nil known

Sponsor number
A097489

Study information

Scientific Title
Pilot study to assess the diagnostic accuracy of a microchip-based Lab-on-Chip system for the detection of genetic biomarkers of colorectal cancer at the point-of-care

Study objectives
This pilot study aims to assess the ability of a microchip-based system to detect human DNA biomarkers of colorectal cancer in stool and blood samples from colorectal cancer patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Single-centre pilot cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Single-centre pilot study to assess the ability of a microchip-based system to detect human DNA biomarkers of colorectal cancer in stool and blood samples from colorectal cancer patients.

Patients diagnosed with colorectal cancer will be contacted to enquire if they would like to participate in this trial. Only members of the patient's existing clinical care team will have access to patient records without explicit consent in order to identify potential participants, check whether they meet the inclusion criteria or make the initial approach to patients to enquire if they are interested to learn more information about the study. If potential participants express interest to learn more about the study, they will be contacted by the research team. Potential participants will be provided with the participant information sheet, study team contact details, eligibility form, consent form and baseline questionnaire. The research team will try to make arrangements for the patients to participate in the study when they attend the hospital for any reason, e.g. when they attend for an outpatient clinic appointment, or for further diagnostic tests, or for treatment, or as inpatients.

Participants to the trial will be asked if they can provide a sample of their blood and stool. This microchip-based test is designed as a point-of-care to test tumour genetic specific to colorectal cancer in blood and stools. The participants will be able to collect a stool sample themselves in their own privacy at home, if possible. Faecal collection kits will be provided to each participant by post or provided when they attend hospital for any reason. A single faecal sample will be collected at home or at the hospital by participants according to instructions within each test kit and guidance will be provided. If participants collect the stool sample at home, they can bring the faecal sample with them when they attend the hospital for any reason, or the sample can be posted. When the participants attend the hospital for any reason, a simple routine venepuncture will be performed, with the patient’s consent, by a qualified healthcare professional or a phlebotomist, to collect a blood sample. There is no actual research intervention, and therefore, no significant risk of harm is anticipated to the patients participating in the study.

The stool and blood samples will be stored at Cambridge University Hospitals, where the samples will undergo chemical processing for the extraction of DNA. Then, they will be transported to Imperial College London to be tested on the microchip-based platform. After testing the faecal and blood samples on the microchip, the samples will be disposed. After they provide their faecal and stool sample, the participants will not be followed up for any period of time.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Microchip-based Lab-on-Chip system

Primary outcome(s)
Detection of colorectal cancer-related human DNA biomarkers in stool and blood samples using the microchip-based system at the time of sample collection from diagnosed patients

Key secondary outcome(s))
1. Adaptation of the microchip-based platform to a panel of proposed colorectal cancer genetic markers measured through assay customisation during the development phase.
2. Optimum configuration of the microchip-based platform for detecting predetermined genetic markers assessed through iterative testing during platform setup.
3. Feasibility of amplification and detection of colorectal cancer-specific genetic targets

evaluated using synthetic DNA during laboratory testing.
4. Ability of chip-based cartridges to multiplex and synchronously detect multiple DNA reactions assessed during assay development for improved diagnostic accuracy.
5. Simultaneous detection of multiple colorectal cancer-specific genetic markers using extracted human DNA measured during laboratory testing of the microchip-based system.
6. Simultaneous detection of multiple colorectal cancer-specific genetic markers in human blood and stool samples assessed using the microchip-based test during sample analysis.
7. Identification of colorectal cancer-specific genetic targets for inclusion on the microchip determined during assay design and marker selection.
8. Feasibility of the microchip-based test as a lab-free, point-of-care tool assessed through evaluation of usability, speed, and accuracy during prototype testing.
9. Ability of the microchip-based test to identify genetic markers for prognostic and predictive categorisation, which can categorise a patient into a high- or low-risk group, assessed during analysis of patient samples.
10. Ability of the microchip-based test to identify genetic markers predictive of treatment response to specific types of treatment (e.g. chemotherapy agents, radiotherapy) and thus guide personalised cancer treatment evaluated during correlation studies with treatment outcomes.
11. Ability of the microchip-based test to monitor treatment response and post-treatment surveillance assessed through serial sample analysis across different therapy types. Different therapies for colorectal cancer include surgery, radiotherapy, chemotherapy, or any combination of these treatments.
12. Stakeholder and patient acceptance and compliance with the microchip-based test measured through interviews conducted during the feasibility study.
13. Dissemination of findings to promote uptake of the microchip-based platform, measured by the number of published papers and scientific presentations during and after study completion.

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Participant is willing to comply with all trial procedures
3. Participant is over the age of 18 years
4. Patient diagnosed with colorectal cancer
5. Patient had histology confirming colorectal cancer
6. Patients at any stage of colorectal cancer will be included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients aged <18 years old
2. People who are unable to give informed consent

Date of first enrolment
01/03/2026

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR Cambridge Biomedical Research Centre

Alternative Name(s)
Cambridge Biomedical Research Centre, NIHR Cambridge BRC, National Institute for Health Research Cambridge Biomedical Research Centre

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Penguins Against Cancer

Funder Name
Red Trousers Day

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Constantinos Simillis (c.simillis@nhs.net).
The researchers will have no access to identifiable personal information until participants have consented to take part in the research study. After patient recruitment research data will be pseudo anonymised (de-identified). Participants will be allocated a unique key study number and the main dataset will contain no personal identifiers.
Data to be collected:
1. Participant details, including name, surname, date of birth, age, hospital number, NHS number. address, phone number and/or email address. Please note that this data will be pseudo anonymised (de-identified). Patients will be allocated a unique key study number and the main dataset will contain no personal identifiers.
2. Histology result of any biopsies
3. As part of the histology report additional genetic information is provided, such as mismatch repair (MMR), or BRAF, or KRAS etc.
4. Record the staging of the cancer (TNM stage) based on histological and radiological

information
5. Result of the microchip-based test based on faeces.
6. Result of the microchip-based test based on blood.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form		28/10/2025	No	No
Other files	Invitation letter		28/10/2025	No	No
Participant information sheet			28/10/2025	No	Yes