ISRCTN92139363 https://doi.org/10.1186/ISRCTN92139363

Evaluation of a novel bowel cancer blood test to prioritise the colonoscopy waiting list

Submission date
12/01/2026

Recruitment status
No longer recruiting

Registration date
20/05/2026

Overall study status
Completed

Last Edited
20/05/2026

Condition category
Cancer

[_] 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
Further colonoscopy tests are usually required after treatment for bowel cancer or after removal of bowel polyps to detect if the cancer or polyp has returned. Many of these colonoscopies are now overdue after they were paused by the COVID-19 pandemic. At present there is no reliable way to tell if a polyp or bowel cancer recurrence is present, aside from performing the colonoscopy. Delays to appointments increase patient anxiety and worry. A technique called Raman spectroscopy analysis of blood serum has shown good levels of accuracy for detecting colorectal cancer and polyps in work to date. The aim of this study is to assess the test performance of a Raman spectroscopy analysis for routine use in a real-world setting.

Who can participate?
Male and female participants aged 18 years and over who are overdue for a colonoscopy or sigmoidoscopy as part of their polyp or bowel cancer follow up

What does the study involve?
This study will recruit participants awaiting a follow-up colonoscopy following bowel cancer or polyp removal from a single university health board. The study will invite participants to have the blood test performed and they will be told the result. This will be compared with a software model created from blood samples from previously recruited patients where the outcome of their colonoscopy was known. Patients having blood test results indicating a high likelihood of a polyp or cancer being present will have the colonoscopy performed with the greatest urgency. Those with a low likelihood of polyp or cancer will have a lower priority appointment. The study will tell us how accurate the blood test is at prioritising colonoscopy so that in future, those at greatest risk of a recurrence of the cancer or polyp will be given priority for a colonoscopy

What are the possible benefits and risks of participating?
The study will improve our understanding of the best way to manage future participants who need colonoscopy procedures scheduled. There are small risks involved with taking a blood sample. These include bruising, bleeding, pain/discomfort, fainting or infection at the local site from which the blood is taken.

Where is the study run from?
Swansea Bay University Health Board (UK)

When is the study starting and how long is it expected to run for?
December 2023 to June 2025

Who is funding the study?
Moondance Cancer Initiative (UK)

Who is the main contact?
Prof. Dean Harris, dean.a.harris@wales.nhs.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Rhodri Stacey

Contact details
Swansea Bay University Health Board
Swansea
United Kingdom
SA2 8PP
+44 (0)1792 205666
rhodri.stacey@wales.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
328257

Study information

Scientific Title
Phase II prospective interventional multi-site performance evaluation trial of serum Raman spectroscopy and supervised machine learning classification in a colonoscopy surveillance population

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2023, Yorkshire and the Humber (NHS Blood and Transplant Blood Donor Centre Holland Drive Tyne and Wear, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0) 207 104 8388; sheffield.rec@hra.nhs.uk), ref: 23/YH/0186

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Single

Purpose
Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Colorectal cancer, high risk polyp and genetic colorectal cancer predispositions

Interventions
Patients on the surveillance colonoscopy waiting list will be invited to provide a blood sample that will be analysed by Raman spectroscopy to determine a risk score for colorectal cancer and /or advanced adenomas. The colonoscopy findings will be compared to the blood test output to determine the test performance (sensitivity, specificity).

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Raman spectroscopy

Primary outcome(s)
1. Raman spectroscopy test sensitivity and specificity compared to gold standard colonoscopy and histopathology; measured using sensitivity: percentage of true positives among the study population who have the condition; and specificity: percentage of true negatives among the study population of those without the condition; at post-colonoscopy

Key secondary outcome(s)

Completion date
27/06/2025

Eligibility

Key inclusion criteria
1. Male or female patients aged over 18 years
2. Overdue colonoscopy surveillance after previous adenoma/colorectal cancer diagnosis
3. Willing to provide evidence of written informed participation
4. Willing to attend for colonoscopy

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
212

Key exclusion criteria
1. History of invasive or haematological malignancy diagnosed within the last 3 years
2. Unwilling to participate
3. Declines colonoscopy
4. Inflammatory bowel disease surveillance

Date of first enrolment
07/12/2023

Date of final enrolment
27/06/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea Bay Cds
One Talbot Gateway

Baglan Energy Park
Port Talbot
Wales
SA12 7BR

Sponsor information

Organisation
Swansea Bay University Health Board

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type

Funder Name
Moondance Cancer Initiative

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available