ISRCTN15709915 https://doi.org/10.1186/ISRCTN15709915

Can neurotensin and IL-8 levels in blood be used to identify colorectal (large bowel) cancer and adenomas (polyps)?

Submission date 02/03/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/03/2019	**Overall study status** Completed	
Last Edited 08/09/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-develop-a-screening-test-for-bowel-cancer-nil

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
261217

Protocol serial number

MB 909

Study information

Scientific Title
The combined use of serum neurotensin and IL-8 as screening markers for colorectal cancer and adenomas. A prospective study.

Acronym
NIL

Study objectives
We have hypothesized that the combined use of serum neurotensin and IL-8 values has superior diagnostic performance than the established follow-up scheme for screening colorectal cancer and adenomas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trial registration is required before ethics approval can be requested through IRAS.

Study design
Multi-center case control study

Primary study design
Observational

Study type(s)
Screening

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

Interventions
All individuals fulfilling the inclusion criteria will be enrolled. After the refinement of participants by the exclusion criteria, blood samples will be drawn for neurotensin and IL-8 testing by ELISA at Lancaster University, after being centrifuged and stored at deep freeze in -80° C in the Pathology Laboratories of Furness General Hospital and Royal Preston Hospital. Colonoscopy and histology reports will be obtained from Electronic patient Records (EPR). Following the report of the colonoscopy and histology departments, individuals will be assigned to one of three groups: group A - cancer patients, group B – adenoma (polyp) patients and group C – no pathology/normal colonoscopy. Two primary analyses will be conducted to define the cut-off plasma values for neurotensin and IL-8 for a) diagnosing cancer (group A versus group C) and b) diagnosing adenomas (group B versus group C). A secondary analysis will be conducted comparing the performance of the neurotensin/IL-8 system towards the 2-weeks referral and faecal occult blood (FOB) test-positive patients for the diagnosis of colorectal cancer and adenomas. There will be no observation or follow-up as part of the trial.
The reason for using participants without bowel pathology is because we need to define the normal range of neurotensin and IL-8 serum values.

Intervention Type
Other

Primary outcome(s)
1. Serum neurotensin measured by Human Neurotensin (NT) ELISA Kit (Cusabio)
2. Serum IL-8 values measured by ELISA (test brand tbc)
3. Diagnosis of colorectal cancer or adenoma using colonoscopy and histology reports

Key secondary outcome(s))
Diagnostic performance compared to the current screening system

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Aged over 50 years
2. Referred for colonoscopy for any suspected indication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Need for emergency surgery
2. Presence of inflammatory bowel disease
3. Known history of inherited colorectal cancer
4. History of cancer in another primary site
5. Presence of liver metastases (since neurotensin is metabolized in the liver)
6. Negative previous colonoscopy for cancer
7. Haemolysis in serum samples
8. Informed consent not signed or patient withdrew consent
9. Persons who will not have the capacity to decide for themselves, who are unable to represent their own interests or are particularly susceptible to coercion

Date of first enrolment
03/06/2019

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Morecambe Bay
Westmorland General Hospital
Burton Rd
Kendal
United Kingdom
LA9 7RG

Study participating centre
Lancashire Teaching Hospitals Trust
Royal Preston Hospital
Sharoe Green Ln
Fulwood
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
University Hospitals of Morecambe Bay

ROR
https://ror.org/05cxwhm03

Funder(s)

Funder type
Charity

Funder Name
Rosemere Cancer Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the researchers have agreed to destroy electronic data relating to participants within 6 months of the last participant enrolment.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.5	16/02/2019	18/10/2022	No	No