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Raman spectroscopy and colorectal cancer

Submission date
23/11/2017

Recruitment status
No longer recruiting

Registration date
03/01/2018

Overall study status
Completed

Last Edited
16/01/2018

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer is one of the commonest cancers worldwide. Earlier detection causes better outcomes for patients and longer survival. Symptoms of bowel cancer are non-specific and are shared by harmless bowel disorders. It is a challenge for doctors in general practice to diagnose bowel cancer and many symptomatic patients are sent to hospital for tests to rule it out. This is normally a colonoscopy, which is expensive, uncomfortable and can be harmful. The current approach to diagnosis causes great anxiety in patients waiting for these tests and is not a prudent approach to diagnosis. To allow earlier diagnosis by GPs we have studied whether a newly designed blood test taken in primary care is accurate and effective in patients with bowel symptoms that could be linked with cancer. This would benefit a large number of patients who are concerned about their bowel symptoms without the need for referral to hospital. It could also lead to diagnosis of bowel cancer at an earlier stage improving survival in the longer term. The aim of this study is to use a newly developed blood test for bowel cancer in primary care to achieve an earlier diagnosis. This would allow more timely appropriate treatment both for patients diagnosed with bowel cancer and those who are cancer free.

Who can participate?
Adults aged 50 years and older who have symptoms of bowel cancer.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their Raman spectroscopy blood test done immediately and those in the second grou have their sample tested after they've had a diagnosis. The amount of participants who are referred on the USC pathway from each group are assessed after 12 months.

What are the possible benefits and risks of participating?
For the patients allocated to the Raman test being conducted immediately, the GP will be notified of the result and can make an informed decision on the planned referral / treatment decision for the patient. A negative Raman result may result in avoiding an unnecessary intrusive investigation of the colon. A positive Raman result will ensure a speedy triage and investigations in secondary care. There are a few risks involved in this trial. The patient is only providing one extra blood sample beyond what would be expected for standard care. There may be a small risk associated with having to fast for the sample but the patient can elect to have their sample taken early in the morning to avoid any potential issues. Additionally, there is a possibility that

we will have false negative tests from the Raman test which may cause a delay in treatment for the patient. However, the GP retains the right to refer the patient on the USC pathway, irrespective of the Raman result.

Where is the study run from?
Abertawe Bro Morgannwg University Health Board (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2017

Who is funding the study?
Welsh Government's Efficiency Through Technology fund (UK)

Who is the main contact?
Dr Kym Thorne (Public)

Contact information

Type(s)
Public

Contact name
Dr Kym Thorne

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Additional identifiers

Protocol serial number
238847

Study information

Scientific Title
RAMAN spectroscopy and colorectal cancer: towards early diagnosis and personalised medicine

Acronym
RAMAN-CRC

Study objectives
Raman spectroscopy can detect colorectal cancer better than current investigations such as colonoscopies and is easier to administer as a blood test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 6 - submission pending

Study design
Randomised multicentre trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
Block randomisation with the intervention arm having their Raman spectroscopy blood test done immediately and the control arm having their sample tested after they've had a diagnosis. Total follow up is 12 months.

Intervention Type
Other

Primary outcome(s)
The proportion of recruited patients who are referred on the USC pathway within the intervention group and compared to the control group at 12 months

Key secondary outcome(s))
1. USC pathway timelines in each group at 12 months:
1.1. Time from first GP appointment to date of referral (days)
1.2. Time from first GP appointment to first appointment in secondary care (days)
1.3. Time from first GP appointment to investigation (CT scan or colonoscopy) (days)
1.4. Time from first GP appointment to final diagnosis (days)
2. Number of patients referred on USC pathway pre/post phase 2 by participating practice at 12 months
3. Number of days on the USC/non-USC pathways pre/post phase 2 by participating practice at 12 months
4. Compliance with USC/non-USC pathway timeframes (62 or 31 days respectively) at 12 months by comparing the referral letter with the guidelines
5. Investigation result (cancer/non-cancer) at 12 months based on the final diagnosis in secondary care/GP records if the patient isn't referred to secondary care
6. Estimate of the false negative rate for Raman test at 12 months based on the patient's diagnosis vs the Raman test result (both arms)
7. Colorectal cancer stage (TNM system) by arm at 12 months if diagnosed with CRC

8. Ability to recruit GP practices to the feasibility trial at baseline – the trialists are aiming for 10 sites currently involved in a cohort study to continue into the RCT
9. Ability to recruit and retain participants into each arm of the feasibility trial at 12 months based on withdrawals, loss to follow up, questionnaire completion
10. Ability to collect patient QoL data at all three time points to be assessed per patient as their journey progresses. The final QoL questionnaire is done when they have a diagnosis which will vary significantly for patients
11. Thematic analysis of the responses to patient and doctor questionnaires and interviews at 2 months post-diagnosis per consenting patient

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 50 years or over at time of presentation to GP symptoms/signs raising suspicion of CRC:
1.1. Rectal bleeding and change of bowel habit (looser stool/increased frequency persisting for 6 weeks
1.2. Rectal bleeding alone without anal symptoms or change in bowel habit persisting for 6 weeks
1.3. Change in bowel habit alone (looser stools/increased frequency) without rectal bleeding persisting for 6 weeks
1.4. Unexplained iron deficiency anaemia, haemoglobin of <110 g/l in men; OR unexplained iron deficiency anaemia, haemoglobin of <100 g/l in non-menstruating women
2. Able and willing to give informed consent to participate
3. Willing to provide a fasting blood sample
4. Willing to grant researchers access to identifiable data to enable result feedback to GP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients in whom a secondary care referral is considered mandatory in the opinion of the GP (e.g. clinically detected rectal or abdominal mass)
2. Patients with a prior history of CRC or other invasive malignancy within the last 5 years
3. Patients with signs/symptoms which require emergency referral to secondary care or A&E (e.g. intestinal obstruction, peritonitis, massive haemorrhage)
4. Patients with genetic conditions associated with CRC (Lynch syndrome and familial adenomatous polyposis)
5. Patients with known inflammatory bowel disease
6. Patient from vulnerable groups

Date of first enrolment
01/02/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Abertawe Bro Morgannwg University Health Board
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Abertawe Bro Morgannwg University Health Board

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Government

Funder Name
Welsh Government's Efficiency Through Technology fund

Results and Publications

Individual participant data (IPD) sharing plan

Swansea Trials Unit will house the trial database and should be contacted to discuss data access on STU@swansea.ac.uk. The data will be pseudo-anonymised to allow linkage of questionnaires and NHS records but these semi-identifiers will be removed long term as they are not required once the links have been made for data entry. Access to the data will require formal application and a discussions concerning which fields are to be released and why. Patients will have to consent to their anonymised information being shared, as well as their samples for up to 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes