

Title of Study: Patient acceptability and clinical effectiveness of combined Raman-FIT testing for colorectal cancer diagnosis in primary care

REC ref: 18/LO/2186

Chief Investigator: Professor Dean Harris

Patient Information Sheet

Brief Summary

Our study will combine the results of a blood sample and a faeces ('poo') sample to see how good it is at predicting whether people have colorectal (bowel) cancer.

It is important to us that people with a negative or a positive diagnosis of colorectal cancer are willing to provide a blood and faeces sample soon after they visit their GP and that we are allowed to look at your medical records to see what your diagnosis was.

If you think that you might be interested in helping our research, please read the information below.

Why is the study being done?

We have developed a blood test which might be able to accurately detect whether or not someone has colorectal cancer. We hope that when we combine this with a faecal test then the combination of both test results will be just as accurate as further tests usually carried out in a hospital. These could be a colonoscopy (which involves passing a camera into the bowel) or a special type of CT scan called a CT colonogram. The new tests we are trying give much faster results and are much cheaper.

We need blood and faecal samples from patients who go to their GP with symptoms which sometimes suggest colorectal cancer and as such, require an urgent referral for the hospital tests mentioned above. By comparing the test results from your blood and faecal samples with your final diagnosis, we hope to prove that our test is just as reliable.

We will be recruiting 800 patients from four Welsh Health Boards to ensure we get enough samples to compare. It is important that we can tell the difference between patients who do have colorectal cancer and those who do not which is why we ask everyone being referred to take part. Please remember that less than 10% of these referrals tend to result in a positive cancer diagnosis.

Why have I been asked to take part?

You have been given this information sheet by your GP because you have bowel symptoms which requires further investigation by the hospital to determine the cause of your symptoms. Just because you have been given this information sheet, you do not necessarily have colorectal cancer.

Do I have to take part?

No, you do not have to take part. It is completely up to you and you can always change your mind at any time. Your care will not be affected in any way.

If you opt not to take part, we would like you to consider completing a short questionnaire to help us understand your reasons for not wanting to take part. This will help us when we design our next study to make it more appealing to patients. If you are happy to do this, the GP will give you a different information sheet and the questionnaire.

When do I have to decide?

Ideally, you will decide once you have read and understood this information sheet and the GP has answered all of your questions. However, it is OK if you wish to take the information away and discuss it with your family and friends. You will need to make another appointment with your GP or practice nurse if you do want to take part and ideally, this will be within one week of your original visit to the GP so that the samples can be taken before any hospital tests.

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What is involved?

Once you have read this information sheet and your GP has answered any questions you may have, you will be asked to sign a consent form. This form lists the different things you will be asked to consent to, some of which will be optional.

Providing a blood sample - The GP will give you a blood sample form and ask you to provide a fasted blood sample. This is a blood sample which is taken before you eat anything that day. We advise that you do not eat anything after 10pm the evening before you plan to give the blood sample. Drinking water is OK. The blood sample will be delivered to Swansea University Medical School where it will be prepared for analysis using a Raman spectrometer. The blood sample test is called the Raman test after the machine used to analyse it. Any blood left over will be stored in a locked freezer in case we need to repeat the test. The Raman spectrometer works by looking at molecules in your blood by shining a light through it. Cancer cells produce a different pattern to normal cells in the blood and a computer programme is being developed to learn to read those patterns. The more samples we can test, both with and without cancer, the better the test will work to predict whether a patient has colorectal cancer.

Providing a faeces sample - The GP will also give you a faeces testing kit called a Faecal Immunochemical Test (or FIT). The test can detect tiny amounts of blood in faeces and will be rolled out as part of standard NHS testing for colorectal cancer in Wales in the future. You will be asked to provide a sample at home, not at the GP practice. You will be asked to place a small amount of faeces in a tube using the instructions provided and send the sample by post to our research laboratory at Cwm Taf Morgannwg University Health Board with a form containing your information. Once the test is complete, the sample will be destroyed.

Interview (optional) - Your GP will also ask you if you would like to be interviewed about your opinions regarding the blood and faeces test compared with the hospital tests that you have been referred for. The interview should take place approximately two weeks after you have received your diagnosis. This may be some months after you enrol in the study, depending on when you are seen in the hospital. This will give us time to record your diagnosis from your medical records and contact you to arrange where and when you would like to be interviewed. Only a handful of people will be selected at random for interview so you may not hear from us. If you are selected, interviews will be done by our researcher by phone or, if necessary, as a home visit, at a convenient time. The interview will be recorded and will be sent to a reputable company to be typed up. The transcripts will be analysed by two researchers who will explore common themes relating to acceptability of the tests compared with current investigations such as colonoscopies.

There is no pressure to agree to the interviews – you can agree to only providing the blood and faeces samples and decline the interview part and that would be OK with us.

If you are not taking part in interviews, then your involvement in the study will end once you have provided both blood and faecal samples. If you consent to be interviewed, then your involvement in the study will end once the interview is completed.

What will happen if I do not want to carry on with the study?

Participation is voluntary, and no reason needs to be given if you wish to withdraw. By not providing blood and faecal samples, we will assume that you have changed your mind and we will record on our database that you no longer wish to take part. If you have already provided a study blood sample and wish to withdraw at that stage we will continue to store and later analyse the blood sample unless you expressly tell us that you would like the blood sample to be destroyed. You can do this by contacting the study manager or chief investigator (see end page for contact details).

Please try to let us know if you have changed your mind about being interviewed by emailing crafft@swansea.ac.uk and we can remove you from our list of people to make contact with to arrange

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What are the possible benefits of taking part?

There are no benefits for you directly, although there may be in the future for you and many others. The results of the combined blood and faeces sample analyses will not be provided to your GP or you as a patient as they are not yet proven to work in predicting colorectal cancer. That is why we are doing this study.

What are the possible risks of taking part?

There are minimal risks involved with taking part. You may feel faint if you end up fasting for too long on the day that you provide your blood sample, so we would encourage you to give your blood sample as early in the morning as possible. You may also experience slight bruising where the blood sample is taken. This is normal for some people who have blood tests but if you are concerned, you should discuss this with your GP.

What if new information comes along?

Sometimes during research, we get new information about the treatment being studied. If this happens, we will tell you about it and discuss whether you want to continue in the study.

What information will you collect?

If you consent to providing blood and faeces samples, you will need to agree to us collecting your name, address, date of birth, NHS number, clinical information relating to your colorectal symptoms and your final diagnosis. This information is needed so that NHS research staff can find your medical records to look for your clinical information and diagnosis. No other information will be looked at. Research staff in Swansea University, where the study is managed, do not have access to the NHS system to identify you.

Access to your records may be required until we have a final diagnosis recorded related to your colorectal symptoms. This could take up to 12 months.

If you consent to being interviewed, you will need to provide more personal information, specifically your name, address, phone number and/or email address so that a researcher can get in touch to arrange an interview date.

How will my information be kept confidential?

Any details about you will remain strictly confidential. Blood samples that are collected for the study will be sent to an NHS laboratory in Morriston and anonymised by an NHS researcher using a unique code.

Once anonymised, blood samples will be transferred to the research laboratory at Swansea University for analysis. Results from the samples will only refer to that unique code, not your name and the results will be recorded alongside your unique study number by the researcher at Swansea University.

The faeces sample will be sent to an NHS Clinical laboratory with your personal details and unique study number. All faeces results will be transferred to Swansea University with only your unique project number and none of your personal details.

Your personal information will be retained by the respective NHS laboratories in a secure environment until the study has ended.

Any identifiable information you consent to providing for the purpose of an interview will be carefully managed by the study and will only be accessible to a limited number of key personnel who need to see it.

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Your interview will be assigned a unique code and any identifiable information such as names and places will be coded and removed.

Swansea Bay University Health Board (SBUHB) is the sponsor for this study based in the United Kingdom. They will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. SBUHB will keep any identifiable information about you for five years after the study has finished.

In accordance with new General Data Protection Regulations (GDPR) guidelines, your right to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at

<http://www.wales.nhs.uk/sitesplus/documents/863/Research%20privacy%20notice%20-%20final.pdf>.

SBUHB will make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from SBUHB and regulatory organisations may look at your medical and research records to check the accuracy of the research study. SBUHB will pass these details to their Research and Development department along with the information collected from your medical records. The only people in SBUHB who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the test results will not be able to identify you and will not be able to find out your name or contact details.

All information will be held on a secure database which is maintained by Swansea Trials Unit and is backed up every night by the Swansea University network. The database can only be accessed by authorised users who agree to abide by data protection regulations.

What happens to my samples?

Your blood sample will be tested in the Swansea University Medical School, which is where the Raman spectrometer is housed. Once testing is complete, we will store the sample until the end of the study. You can consent to us keeping any excess sample for use in other research projects if you would like this. Please note that any different research studies wanting to use your sample will need ethical approval to be granted first.

Your faeces sample will be tested at Cwm Taf Morgannwg University Health Board research laboratory. Once testing is complete, the sample will be destroyed.

What will happen to the results of this study?

We hope that the results of the study will help to prove that the blood and faeces sample combination is a good indicator of whether or not someone has colorectal cancer. We also hope to prove that patients and healthcare professionals are willing to use the test as part of standard care if it were to be made available in the future.

The combination of the Raman and FIT could be used in the future to provide a quick answer as to whether or not your GP should send you for a colonoscopy or equivalent procedure. As these procedures are expensive and have long waiting lists, we hope that our tests will provide some quick reassurance for those who test negative and for those with positive blood and/or faecal tests, the patient should have priority for any further investigations.

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You will be asked to give permission for some quotations to be used anonymously in any future presentations and publications. You do not have to agree to this.

If you would like a copy of the final study report (not individual results) this will be through our study's Twitter page. You can however request a mailed newsletter of CRaFT results at study completion by contacting the Study Manager (details below) or returning the contact card provided.

Will I be paid for taking part?

Unfortunately, we are unable to offer any money to people who agree to take part.

Who has funded and reviewed this study?

The study has been funded by the Welsh Government's Research for Patient and Public Benefit funding scheme.

The study documentation has been reviewed by London City & East NHS Research Ethics Committee.

What if there is a problem?

If you have any concerns about your NHS care, please discuss this with your GP.

If you have any questions or concerns about your participation in this study, please contact:

<p>Professor Dean Harris</p> <p>Chief Investigator</p> <p>Morrison Hospital, Swansea Bay University Health Board</p> <p>Dean.A.Harris@wales.nhs.uk</p> <p>01792 285459</p>	<p>Dr Kayleigh Nelson</p> <p>Study Manager</p> <p>Swansea Trials Unit, Swansea University</p> <p>craft@swansea.ac.uk</p> <p>01792 606621</p>
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Alternatively, if you wish to speak to an independent person, you should contact your local Community Health Council:

Swansea Bay Community Health Council
First Floor, Cimla Hospital, Neath SA11 3SU

Tel: 01639 683490

If we cannot resolve your concerns or problem, then Swansea Bay University Health Board has an NHS complaints procedure. Please write to:

Tracy Myhill, Chief Executive, Swansea Bay University Health Board, One Talbot Gateway, Baglan Energy Park, Port Talbot, SA12 7BR. Telephone: 01639 683363; Email: ABM.complaints@wales.nhs.uk