PARTICIPANT INFORMATION SHEET

Plasma biomarkers in stratifying patients referred via the lower gastro-intestinal (LGI) suspected cancer two-week wait (2WW) pathway
IRAS:321809
MOTION study

We would like to invite you to take part in a research study. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to family, friends, or health professionals about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who to contact?

If you have any questions about the study or if you would like a large print version of this information sheet, please contact:

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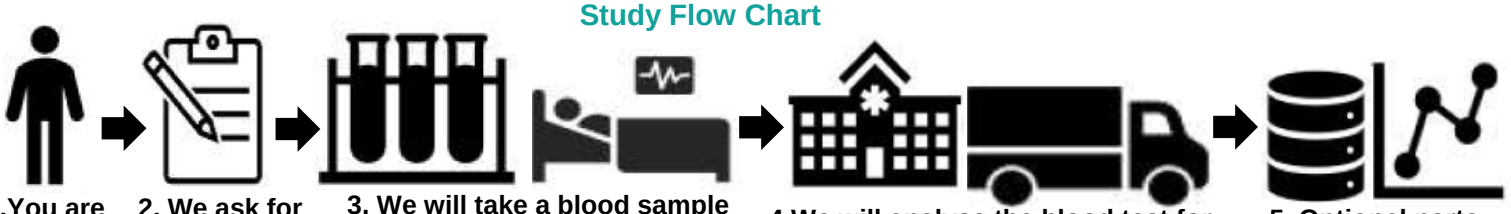
Study Flow Chart



1.You are invited to take part in this study.

2. We ask for your consent

3. We will take a blood sample with your consent.

This blood test is in addition to the standard tests (e.g. Colonoscopy/CT scan) used to diagnose bowel cancer.

4.We will analyse the blood test for cancer biomarkers.

We will compare the results with your final diagnosis.

5. Optional parts:
a. End of study questionnaire may take 10 – 15 minutes.
b. Storage of blood sample for other studies.

1. What is the purpose of the study?

This study wants to see if a blood test can help doctors to identify people who might have cancer in their bowel. When people have symptoms that are highly suspicious for cancer diagnosis, their doctor (GP) may refer them for a special check-up with a specialist via the Two-Week Wait (2WW) or Straight to Test (STT) pathway. The 2WW/STT are bespoke pathways aimed at rapidly processing patients referred with suspected cancer symptoms to enable early diagnosis. By using a blood test, doctors might be able to tell who needs to see a specialist right away. This could help reduce the pressure on the healthcare system and ensure that people with cancer get the care they need as soon as possible.

One of the blood markers described is progastrin. Progastrin is the precursor form of a natural hormone (chemical) called gastrin, which controls the growth of cells of the inner lining (mucosa) of the stomach. It also regulates the acid production in the stomach. In healthy people, progastrin is converted to gastrin by a natural process and is, therefore, not detected in the blood. However, recent studies have shown an increase in progastrin levels in the blood of patients with both early and advanced cancers, including bowel (colorectal) cancers. More research is required to confirm if a raised level of progastrin in the blood can accurately detect the presence of colorectal cancers.

In addition to progastrin, scientists are also studying parts of our DNA called transposable elements (TEs). TEs can move around in our DNA and sometimes disrupt genes. Recent research has found that TEs are linked to different types of cancer, including colorectal cancer (CRC). But we don't know much about how TEs can help predict if someone has CRC when they are referred for a 2WW/STT check-up.

Therefore, this study aims to identify through a blood test people who may have bowel cancer. We will analyse your blood sample and measure the progastrin level. In addition, we will randomly select a sub-group of participants and will test their blood samples for TEs. We will correlate your tests results with the outcomes of your camera test (colonoscopy) and/or CT scan (computed tomography colonography). The blood test will be an additional test taken for the purpose of the study and is not part of your standard care.

Also, the study team want to understand how people like you feel about the different tests that we use to detect colon cancer. By learning about your preferences, we can help doctors and researchers develop better screening strategies. At the end of the study, you will be invited to complete a short online voluntary survey. This survey should take about 10-15 minutes to complete. In the survey, you will be given information about different colon cancer screening tests, including how they're done, how often they need to be repeated, their accuracy, and potential side effects. You will be asked to choose the test you prefer based on the information provided. If you're uncomfortable answering any question, you can skip it. Your answers will be kept completely confidential.

Your insights might help researchers develop more effective and patient-friendly screening strategies.

This study is conducted in partial fulfilment of the requirements for the Doctor of Medicine by Research MD(Res), a postgraduate qualification program registered at Queen Mary University of London (QMUL).

2. Why have I been invited to take part in this study?

You have been invited to take part in this study because your hospital clinic is participating in the research, and your clinical care team believes you may be eligible. They reviewed your medical records and found you may be a good fit as you have been referred to the two-week wait (2WW) colorectal clinic, and your GP (general practitioner) thought you would require tests to rule out bowel cancer.

3. Do I have to take part?

Your involvement is entirely **OPTIONAL**. It is up to you to decide whether or not to take part because participation in the research study is completely voluntary. We will describe the study throughout this information sheet, which you can keep. You do not have to decide today; the research team will call you before your next appointment, and we will ask you for a decision at your next hospital appointment. If you do agree to take part, we will collect the blood sample before your 2WW investigation. Even if you agree, you are free to withdraw at any time without giving a reason. Your decision to take part or withdraw will not affect the standard of care you receive.

4. What will happen if you decide to take part in the study?

Before you decide to take part, a member of the research team may ask you some questions to confirm your suitability for the trial, and they will answer any questions you may have.
Consent: If you decide to take part, you will be asked to sign a consent form. This form confirms you are happy to take part and gives permission for your data to be used as part of the study called "Plasma biomarkers in stratifying patients referred via the lower gastro-intestinal (LGI) suspected cancer two-week wait (2WW) pathway" You will sign the consent form during your hospital visit and when you meet the research team member in person.
Once you give your written permission, a member of staff will take a single 20 ml (milliliters) sample of your blood. The research team will then ask you some questions about your symptoms and general health. This will also be done during your clinic visit. A letter will be sent to your general practitioner (GP) informing them of your participation in the study. If we have any concerns about your health, then you will be made aware, and with your agreement, your GP will be informed, and a referral may be made to a medical team who can help with the problem.
At the end of the 2WW pathway, approximately 3-4 weeks after your initial referral, the study team will contact you to complete the survey. The link for the survey will be emailed or texted to your email or phone number, depending on your preference. If the questionnaire is not received by the research team after 2 weeks have passed, a phone call will be made, or an email will be sent (depending on your preferred route of communication). A second contact will be made after another 2-5 days if the questionnaire has still not been received.

5. What are the possible disadvantages and risks of taking part?

We do not foresee any risks or disadvantages if you decide to take part in the study. After your blood is taken, we will invite you to stay seated for a few minutes to ensure that you feel well enough before you get up again. You will be asked to give up some of your time to answer the general health questions. You may be asked some sensitive questions about your symptoms.

6. What are the possible benefits of taking part?

There are no direct benefits to participating in this research. Participation in this research will not be accompanied by any financial compensation for participants. You will receive the appropriate health

care by your consultant whether you choose to participate in the study or not. However, by taking part in this study, you will be directly helping us to understand whether a simple blood test will give us more accurate information about whether future patients do or do not have bowel cancer.

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

You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive now or in the future. We will keep your data up until the point that you withdraw, and we will not collect any new information from you.

8. Will my taking part in this study be kept confidential?

We will need to use information from you and from your medical records for this research project. This information will include your initials, NHS number, contact details, your health problems and reason why you have been referred to us as well as a history of your symptoms and the results of any relevant tests that you have had done. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
Mr.Mohamed Thaha and members of his research team from Queen Mary University of London are responsible for looking after your information. We will not share your information related to this research project. We will keep all information about you safe and secure by:

- Collecting the data will be entered into a secure database (RedCap) fully regulated by Queen Mary University of London.
- This complies with the Data Protection Act (2018) and uses industry-standard techniques to provide security. Only authorised users with permission can access this data.

Your data will not be shared outside the UK. We will keep your study data for a maximum of 5 of years. The study data will then be securely archived or destroyed. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet
- by asking one of the research team
- by sending an email to any member of the study team provided in the beginning of this document

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The study data will then be fully anonymised and securely archived or destroyed.

9. What will happen with the results of the research study?

The results of the study will be used to improve the diagnostic pathway of patients with suspected bowel cancer. These findings will also be published in scientific journals and presented at scientific meetings. We will write a report for the LAPResearch UK, the medical charity which is funding the study. The findings will also be made available to patients through patient organisations, and health information websites that are open to the public and the media where possible and appropriate.
At the end of the study, participants will have the option to receive their individual results. During the consent process, participants will be asked about their preferred method for receiving these results.

10. Blood sample and clinical information

Your blood sample will be given a study number. The anonymised blood sample will be stored in a secure freezer within the Blizard Institute of Queen Mary University of London . A part of it will be analysed at the laboratories of Biodena Care, Progastrin Manufacturing, Cap Sigma, 1682, rue de la Vasière, 34790 Grabels, France. The remaining part will be stored in the Blizard Institute, Whitechapel at the National Bowel Research Centre laboratory, and will be used for DNA and RNA testing to find new biomarkers to detect colorectal cancer. The blood sample and your clinic information will be treated as strictly confidential and will be securely kept and managed in accordance with the General Data Protection Regulation (GDPR) and all statutory, clinical and research governance procedures. For all consented patients, we will retain the blood samples for 5 years for future ethically approved research projects after which time all samples and clinical data will be securely destroyed.

11. What if there is a problem?

If you have any concerns about any aspects of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the beginning of this information sheet. If you wish to seek advice or reassurance about your own health, then contact your GP.

If you remain unhappy and wish to complain formally, you can do this by contacting the local NHS PALS team (Patient Advice and Liaison Service):

Address: Patient and Family Contact Centre, Ground Floor, Royal London Hospital, Whitechapel, London E1 1FR
Telephone: 0203 594 2040/ 42050
Email: BHNT.centralcomplaints@nhs.net; PALS@bartsandthelondon.nhs.uk

Queen Mary University of London is insured to protect research participants. Your well-being will always be our priority. We believe that this study is safe and do not expect you to suffer any harm or injury because of your participation. However, Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated.

In such a situation, you will not have to prove that the harm or injury which affects you is anyone's fault. These special compensation arrangements apply where harm is caused to you that would not have occurred if you had not taken part in the study. These arrangements do not affect your rights to pursue a claim through legal action.

12. Who is organising and funding the research?

The project is being carried out by a team of researchers from National Bowel Research Centre within Blizard Institute, Queen Mary University of London. This study is funded by the LAPResearch UK (Charity number: 1130523), a medical charity registered in the UK.

13. Who has ethically reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion byt HRA and Health and Care Research Wales (HCRW) Approval (REC reference:24/SC/0416)

Thank you for taking the time to read this information sheet, we hope that it has been helpful in enabling you to decide if you would like to take part in our study

"Plasma biomarkers in stratifying patients referred via the lower gastro-intestinal (LGI) suspected cancer two-week wait (2WW) pathway.

This information sheet is for you to keep.

If you would like to talk to someone in more detail or have any questions then please contact the study team, on 020 7882 8747 or email v.butnari@qmul.ac.uk