



Cost-effective multi-cancer early detection by measuring patient plasma amino acid cross sections with the Enlighten test

Participant Information Sheet B

Study Title: MODERNISED

Chief Investigator: Professor Andrew Davies

Sponsor Reference: RHM CAN1855 **IRAS:** 338326

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide whether to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the purpose of the study?

The purpose of the study is to develop new blood tests to help early identification of different types of cancer. Early diagnosis of cancer is key for better survival and often allows patients more treatment options.

In this study we want to test the performance of a new blood test called “Enlighten” which measures the body’s immune response to early cancer development.

How many people will take part in the study?

About 1350 people will take part in this study: 1000 participants with a cancer diagnosis, 250 participants without a cancer diagnosis but showing signs and symptoms of cancer and 100 participants who are fit and well (healthy volunteers).

Why have I been chosen?

You are being asked to take part in this study because you are over the age of 18 years and you have been referred to hospital with possible symptoms of cancer for investigation.

Do I have to take part?

No. Your participation is voluntary. It is up to you to decide whether or not to take part. If you decide not to take part it will not affect the standard of care you receive.

What will happen to me if I take part?

At your hospital appointment, a research team member will check if you are suitable for the study. If you are suitable, you will be asked to take part and, if you are happy to do so, sign a consent form.

After you have signed the consent form, a research team member will confirm your eligibility by reviewing your medical records and asking you questions about your health. We will also collect some background information about you, such as your age, sex, ethnicity and socio-economic status. A trained member of the research team will collect an additional 4mL (just under a teaspoon) of blood from you to be used in the study. This amount of blood will allow us to complete all the tests required for the study and to allow us to have backups if a test needs repeating. You will not be required to attend any further visits for the study.

Signing the consent form will also give the study team permission to check your health status from medical records and NHS registries. We would like to collect information on the results of tests and appointments you have, plus any diagnosis of your symptoms and how that is treated for up to 2 years after enrolment in the study.

Taking part in the study should not add more than approximately 30 minutes to your standard appointment.

If your health status changes during the course of the study, we will continue to analyse your data but the results from your blood test may be grouped with different participants for study analysis. This will have no effect on the treatment and care you receive.

What are the possible benefits of taking part?

Participating in this study may help improve care for people by detecting cancer early when there are more treatment options available. You will not find out the results of the test. The data we get from you will help future patients and may also help doctors to know how the Enlighten test could help patients at risk of cancer.

What are the possible disadvantages and risks of taking part?

You will need to give a blood sample. Although this process is generally safe you may experience some minor but short-lasting discomfort or bruising. If blood needs to be taken as part of your hospital care, the research blood sample will be taken at the same time.

What will happen to my blood sample?

Samples you donate will be coded with a unique study specific code number so that you cannot be personally identified. Your coded blood samples will be transferred to the University of Southampton's Wessex Investigational Sciences Hub (WISH) for processing and analysis using the Enlighten test. We will then send the test results to Proteotype Diagnostics, who developed the test. At the end of the study, the results from all the participants will be looked at together to see if the test is able to detect cancer. The results from your blood test will not leave the UK/EU.

We would also like to keep any of your blood sample not used for the test so that we can use it in other future research studies. For this we may send scientists at other organisations, including private companies located within the UK or abroad, part of your donated sample for analysis at collaborator's laboratories. The use of your blood sample in these future studies will only be carried out if further review and approval is provided.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your initials, month and year of birth. 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 initials, month and year of birth. Your data will have a code number instead.

University Hospital Southampton NHS Foundation Trust is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- We will protect your identity by using a study specific code number instead any identifiable information
- We will keep all information about you in an access restricted database for the duration of the study
- Only delegated and trained research staff will have access to your information

We would also like to keep your data so that we can use these for any applicable future research studies. The use of your data in these future research studies will only be carried out for the duration of those new studies if further review and approval is provided.

International transfers

We may share data about you outside the UK for research related purposes to:

- Your data may be used for future ethically approved research projects
- Your data may need to be stored on secure servers within the EU and within the United States

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Research partners who analyse your data
- Organisations who store your data

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK

- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

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.

We will keep your study data for a maximum of 15 years. The study data will then be fully anonymized and securely archived or destroyed.

What are your choices about how your information is used?

- 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 remove, change or not use data we hold about you for the purposes of the study. 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.

Where can you find out more about how your information is used?

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 - www.hra.nhs.uk/patientdataandresearch
- By contacting the study Sponsor's Data protection Officer at
 - email: dataprotection@uhs.nhs.uk
 - Telephone number: 023 8120 5079

What happens when the research study ends?

After the research study ends, you will continue being followed up as usual with your own clinicians. After study completion, we may use hospital records, the NHS cancer registry data or other appropriate NHS data repository to see who received a cancer diagnosis. If you have any ongoing concerns following the completion of this research study please discuss these with your doctor.

What will happen if I don't want to carry on with the study?

You can decide to stop participating in the study at any time. You do not have to give a reason. If you no longer want to remain in the study please inform the research team. This will not affect the standard of care you receive.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

You can also tell us if you no longer want the samples that you provided to be used in the study.

If you choose to stop participating in the study, we will destroy any unused or leftover samples you have provided.

Will my taking part in this study be kept confidential?

Your personal data will be kept in a coded form and only a few accredited research team members will be informed if they strictly need it for this study.

Organisations that may look at your collected trial data for verification of procedures and data, research, quality assurance, and data analysis include:

- University Hospital Southampton and Southampton Clinical Trials unit
- Proteotype Diagnostics Ltd
- REC/HRA and government agencies involved in keeping research safe for people

All will have a duty of confidentiality to you as a research participant. We will keep your data safe and in a secure environment in accordance with NHS England guidelines. We will make sure no-one can work out who you are from the reports we write.

Analysis of deidentified data will be conducted by the research team at Clinical Trial Unit (University of Southampton) and Proteotype Diagnostic Ltd. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your blood sample will be coded and labelled with your study specific code number so no one can work out your identity from your sample. Coded is not the same as anonymous. It will be possible to use the codes to identify that a result is from your sample. However, we do not plan to do this unless there is a good reason to do so. We will maintain this information so that we can properly manage the samples.

Involvement of the General Practitioner/Family Doctor (GP)

Your GP will be informed of your involvement in the study. Your GP will not be notified of your test result.

What will happen to the results of the research study?

Once the study is complete a report will be written and the results will be published to make them available to the public. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What rights do I have to the results of the research?

Any information derived directly or indirectly from this research, as well as any patents, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this research may be used for commercial purposes. You have no right to this property or to any share of the profits that may be earned directly or indirectly as a result of this research.

Who is organising and funding the research?

University Hospital Southampton NHS Foundation Trust is the sponsor of this study and is partnering with the Southampton Clinical Trials Unit, the Southampton Experimental Cancer Medicine Centre (ECMC, based at the WISH laboratory) and Proteotype Diagnostics Ltd. The study is funded by the National Institute for Health and Care Research (NIHR). The study will be run by the Early Diagnosis team at the Southampton Clinical Trials Unit, a team of cancer researchers based at University Hospital Southampton NHS Foundation Trust.

Who has reviewed the study?

A Research Ethics Committee has reviewed the study and provided it with a favourable opinion.

What if there is a problem?

If you have a concern about any aspect of this study, speak with the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through NHS Complaints Procedure, via the Patients Advice and Liaison Service (PALS). PALS can provide confidential, impartial advice regarding concerns and complaints. PALS helps to improve the NHS by listening to your concerns and suggestions.

You can reach the UHS PALS team via:

- Email: pals@uhs.nhs.uk
- Telephone: 023 8120 6325
- Post: Patient advice and liaison service (PALS), Mailpoint 81, Southampton General Hospital, Tremona Road, Southampton, SO16 6YD

If you are harmed by taking part in this research project and this is due to someone's negligence, then you may have grounds for compensation against the NHS Trust where you are being treated, but you may have to pay for your legal costs.

Contact for Further Information

Should you have any further queries regarding this study

Please contact:

Lead Nurse: xxxx

Email: xxx

Contact Number: xx

Thank you for taking the time to read and consider this information sheet. Should you decide to take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.