Refining Ovarian Cancer Test Accuracy Scores:

A test accuracy study to validate new risk scores in women with symptoms of suspected ovarian cancer

The ROCkeTS-GEN Validation Study 2

Chief Investigator: Prof Sudha Sundar

Patient Information Sheet

Thank you for taking the time to read this information sheet. We understand that this may be a very difficult time for you. This leaflet explains our research study so you can decide if you would like to participate and help us find the best way to detect ovarian cancer in women with ovarian cysts.

We know that people in this situation often need extra support, so at the end of this leaflet, we have put the contact details for organisations that can help you.

Brief summary

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it will involve for you.

A member of our research team will go through this information sheet with you to help you decide whether or not you would like to take part and to answer any questions you may have. Please feel free to discuss the study with your partner and others if you wish.

This Patient Information Sheet tells you the purpose of the study, what will happen if you decide to take part, and provides detailed information about how the study will be conducted. Please take the opportunity to ask any questions and to ask for more information if anything is unclear.

Purpose and background to the research

We know that lots of women have symptoms such as bloating and abdominal discomfort. It is also very common to have cysts (balloon like swellings) on women's ovaries, picked up by ultrasound. In addition, some women have higher levels of a blood marker called CA125. This blood test can be abnormal in many conditions, including menstruation, fibroids, appendicitis etc. A very small number of women with ovarian cysts or abnormal CA125 levels will be diagnosed with ovarian cancer.

The purpose of this study is to identify better tests for women with ovarian cysts or abnormal blood test results so we can detect ovarian cancer earlier. This will also reduce unnecessary tests, hospital visits, and distress for women who don't have cancer.

Why have I been invited?

You have been approached to consider taking part in the study because you have an ovarian cyst or a blood test indicating raised levels of CA125, and you are post-menopausal.

What would taking part involve?

If you agree to take part in this study, you will be invited to answer a few questions about your symptoms, donate a blood sample (about two tablespoons – 30ml), and provide a few blood spots from your finger (around 3-6 drops, equivalent to 0.1-0.2ml). We will do our best to take the blood samples for research at the same time as any other routine blood tests your doctor wants you to have. During this study, you will have tests and procedures that are part of your usual care. The blood samples will be sent to a University of Cambridge and/or Queen Mary University of London laboratory for testing, and will be stored in a dedicated facility that allows us to look at them closely.

If your doctor advises surgery or biopsy, then we will collect a small sample of your tissue that will be sent to the University of Cambridge and/ or Queen Mary University of London laboratory.

If you don't need to have surgery, you will be contacted by the trial team in 12 months, depending on your care plan. This will be either through a clinic visit - if your doctor wants to see you at the same time - or via a telephone call from your hospital to ask how you are doing. Alternatively, a research nurse may look up your health status in hospital records.

If some of the follow-up information is unavailable through the medical records accessible to the research team, your GP may be contacted directly by the research team to enable the collection of this information.

Will taking part in the study change my treatment?

Your care plan will not be affected by taking part in this trial. Your doctor will continue to manage your care according to their clinical assessment and in accordance with standard of care guidelines.

What are the possible benefits of taking part?

Participating in the study may help doctors determine the best tests and treatments for other women in the future who have similar symptoms.

At this time, we don’t know how accurate the new tests are. We are going to check how accurate these tests are on the samples we have collected from you. Therefore, the doctors treating you will not have access to the blood test results from the research study.

What are the possible disadvantages and risks of taking part?

The side effects from donating a blood sample - about the volume of two tablespoonfuls, about 30ml - are usually minimal. Occasionally, some patients may experience some bruising at the site, which typically settles within a day or two.

What if I do not want to take part?

If you do not want to take part in the study, this will not affect the care you receive in any way.

If you do decide to take participate but later change your mind, you are free to withdraw from the study at any time. You don’t have to give a reason why you have changed your mind. If you choose to withdraw from the study, any information already collected about you will still be retained and used in the study.

Sample storage

Your blood sample will be transferred for analysis to the University of Cambridge and/or Queen Mary University of London. The samples will be stored until the end of the study, after which they will be transferred to a licenced research biorepository (Barts Cancer Institute, Queen Mary University London, Charterhouse Square, London) to support future, ethically approved research studies indefinitely. The samples will not have your name on them and will be pseudonymised - which means they will be labelled with a unique number instead of your personal details. Only the research team will be able to link this number to you.

If you have surgery or a biopsy and a tissue sample is taken, it will also be sent for analysis to the University of Cambridge and/ or Queen Mary University of London. Depending on the local practice of your hospital, the tissue sample may initially have some of your personal details, such as your hospital number or NHS number, stamped on the material it is preserved in. However, this information won’t be kept by the laboratory. When the laboratory staff receive the sample, they will process it to ensure it is pseudonymised and turn the sample into slides for analysis. Any remaining tissue sample will be returned to your hospital. DNA extracted from the tissue samples will then be stored for analysis.

Will taking part in the study be kept confidential?

In this research study we will use information from you, your medical records and your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe, secure and confidential. We will also follow all privacy and data protection regulations.

At the end of the study, we will save some of the data in case we need to check it **AND/OR** for future research.

We will make sure you cannot be identified from the reports we write.

How will we use information about you?

The University of Birmingham will need to use information from you, from your medical records and from your GP for this research project.
This information will include your

- **Personal information**—initials, name, age, date of birth, ethnic group, education level, employment status, marital status, and contact details
- **NHS number**

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 and samples will have a code number instead.

The University of Birmingham is the sponsor of this research. The University of Birmingham is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- University of Cambridge
- Queen Mary University of London

We may use your samples to conduct research with researchers based both inside and outside of the UK. It is possible that collaborative researchers may include researchers working for commercial companies based in other countries. In that case, we will ask for ethics permission to do this and we will not share any information that identifies you.

We will keep all information about you safe and secure by:

- Using secured online database (REDCap)
- Anonymise your samples

We will not share your information with any third parties for the purpose of direct marketing.

Sometimes, external organisations assist us with processing your information, for example in providing IT support. These organisations act on our behalf in accordance with our instructions and do not process data for any purpose over and above what we have asked them to do. We make sure we have appropriate contracts in place with them to protect and safeguard your data.

Researchers at the University of Birmingham will securely store details of your NHS number, name and address and date of birth. Your identifiable information which includes NHS number, name and address and date of birth will be used to request data to support this study from the Health and Social Care Information Centre. The data requested will be from the cancer registry, HES (hospital episodes statistics) dataset and the COSD (cancer outcomes and services dataset) to assist with our analysis.

How will we use information about you after the study ends?

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 identify you. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised 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. However, we will keep information about you that we already have.

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

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you access or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research that uses your data saved from this study.

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

The University of Birmingham's web page 'Data Protection - How the University Uses Your Data' provides detailed information about how to ask any questions you may have, how your personal data is used, exercise any of your data protection rights, or make a complaint about the way your data is being handled.

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, through the following:

- Our leaflet (www.hra.nhs.uk/patientdataandresearch)
- By asking a member of the research team
- By sending an email to rocketsgenv2@contacts.bham.ac.uk,

Who is the data controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary to do so for our research, which is a task we carry out in the public interest.

Your rights

The information you provide will be managed as required by Data Protection Law. Should you decide to take part, your rights to access, change or move your information are limited, as we need to manage your information in specific ways 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 by contacting us (details at the end of this information sheet).

Will my GP be informed?

With your consent, your GP will be informed that you are taking part in the ROCkeTS-GEN V2 Study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called the Research Ethics Committee. Their role is to ensure your rights as a participant are protected and to ensure the research being conducted is ethical. This study has been reviewed and given a favorable opinion by the East Midlands – Derby Research Ethics Committee.

Who is organising and funding the research?

This research is being funded by Cancer Research UK (CRUK) and co-ordinated by the University of Birmingham.

No one involved is being paid for recruiting women into the study. Patients are not paid to take part either, but their help with this research means a lot to the research team. The University of Birmingham will be acting as study sponsor. Representatives of the sponsor may wish to look at your medical notes to ensure that the study has been carried out to the highest quality.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to a member of the local research team, who will do their best to answer your questions.

If you are still unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the hospital's PALS (Patient Advice and Liaison Service) Office or Patient Advice and Support Service in Scotland. They offer confidential advice and will advise you how to contact someone for independent advice. You will find your local office contact details at the end of this leaflet.

What will happen to the results of the research study?

The results of this study will be reported in a medical journal and talked about at medical conferences. It is expected that the first results will be published about two years after the study finishes recruiting women. A summary of the results will be available on the trial website…………………………………………………..

Do you have any further questions?

Thank you for taking the time to read this information. If you have any questions, then please feel free to get in touch with us using the contact details at the end of this leaflet.

I want to know more about Ovarian Cancer

Both Target Ovarian Cancer: targetovariancancer.org.uk/ and Ovacome: www.ovacome.org.uk/ are excellent sources of information on Ovarian Cancer, should you wish to know more about the disease.

Printed leaflets with further information about ovarian cancer are also available from your study consultant or GP.

CONTACT INFORMATION

If you would like to speak to someone about the study, please contact the study team at:

Rocketsgenv2@contacts.bham.ac.uk

Or speak to your local site study team at:

SITE CONTACT DETAILS

Support can also be found through the NHS Patient Advisory and
Liaison Service (PALS) equivalent
(Patient Advice and Support Service in Scotland)

ATTACH LOCAL PALS
INFO STICKER HERE