PRECISION HBOC

Stratifying Risk for Early Detection in Hereditary Breast and Ovarian Cancer

Participant Information Sheet

v2.0 - 18 Nov 2021

You have been invited to take part in the PRECISION HBOC (Hereditary Breast and Ovarian Cancer) study because you are having predictive (presymptomatic) genetic testing.

Please read the following information carefully. This will help you to decide on whether you want to take part in the study or not. There is no obligation to take part, and if you wish not to, the care you would normally receive from your GP and from other NHS organisations will not be affected in any way.

If anything is not clear, or you would like more information please get in touch using the contact details provided at the end of this leaflet.

The Precision HBOC Study is being organised by the University of Cambridge and is funded by Cancer Research UK. [Cambridge University Hospital NHS Foundation Trust or local site] and the University of Cambridge are joint sponsors for this study. A sponsor takes on responsibility for initiation, management and arranging the financing of the research.

Part 1 – A brief summary of the study

Why is the study needed?

We have developed a new tool called CanRisk, which gives each woman with a mutation her own personal risk estimate based on factors that are known to modify the risk. One of the most important factors is the combined effect of hundreds of small genetic alterations scattered throughout someone's genetic material that act together to increase or decrease a woman's cancer risk, and which will be different for each person. These small genetic factors can be added together to create what is called a Polygenic Risk Score (PRS). Other factors include hormonal (e.g. age at first period, number of pregnancies) and lifestyle (weight, alcohol consumption). The CanRisk personalised risk estimate has been validated and we know it correctly identifies those at higher risk. This study will examine how we can best use it in the clinic and how it influences women's uptake of early detection and risk reduction.

Part 2 – What will I have to do?

Give Consent to take part in the study

The consent form asks for your permission to access and use specific information from your medical records. We will collect this information from Breast Units, the Cancer Registration Data held by NHS digital (on behalf of Public Health England) and your GP. NHS digital will also be able to provide us with information from the civil registration data about any deaths so that the data we hold is as accurate as possible. If you decide to participate you will be offered genetic testing in the standard way in an NHS Clinical Genetics service. Should the test show that you have inherited the mutation running in your family you will then be randomised to one of two groups:

1. Receive a conventional risk estimate in the conventional way (control group)
2. Receive a personalised risk estimate based on additional analysis of your DNA sample to look for genetic modifiers and a combination of the other risk factors as described above.

Regardless of which group you are randomised to, your care will remain under your NHS Clinical Genetics service.

Complete some questionnaires

We will ask you to complete some questionnaires. You will be able to do this online (on a PC, tablet, or smartphone) or if you prefer, on paper. Each questionnaire should take no more than 20 minutes to complete. The first questionnaire will include questions about your thoughts about risk management, your medical history, your hormonal factors (e.g. age at first period, number of pregnancies) and lifestyle (general health, weight and alcohol consumption). Further questionnaires at 1, 3 and 12 months will ask about your planned management (surveillance, risk-reducing surgery) and how you found the testing experience. We will also ask you for some personal information (see Part 3 – Your Data).

Interviews

We will approach some participants to ask if they would be willing to be interviewed by one of the research team so we can find out about their experiences in more detail.

How might I benefit from taking part in the study?

You will receive a different risk estimate depending on which group of the study you are randomised to. This could involve additional analysis to your standard genetic test (the analysis will be done on the same blood sample you gave for genetic testing). Our aim is to study how these differences affect your subsequent decisions regarding your medical management. There is no direct benefit to you. However, by taking part in our research study you will potentially be helping future generations of women like yourself.

We will publish our findings on our website and/or in a newsletter.

Will there be any disadvantages if I take part?

We will use the sample blood sample as the one for your genetic test. No additional blood test will be required. There are no medical risks in taking part.

What should I do now?

If after reading this information sheet you decide you would like to take part in the study, please complete the consent form. This consent form can be accessed via the QR code or website link found in the cover letter and study flyer attached. Please contact us if you require a paper version of this consent form.

Part 3 - Your Data

What is data?

Your personal details including your name, address, contact details, date of birth, NHS number (i.e. anything that could identify you) are called "personal data". Other information we collect from you throughout the course of the study is called "research data". We will use information from you, from your medical records, your GP and from NHS Digital for this research project.

Will the use of my data meet GDPR Rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Only the research team will have access to your personal information but sometimes people from the sponsor and other regulatory organisations may need to check our records to make sure that the research is being done properly.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS Research Ethics Committee (REC) checks this before the research starts.

This study has been reviewed and given a favourable opinion by National Research Ethics Service (NRES) Cambridge South, Reference Number: 21/EE/0062.

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, NHS number, name and contact details. 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.

We will keep all information about you safe and secure.

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.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, 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 see 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 using your data saved from this study.

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

You can find out more about how we use your information at:
www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/
www.hra.nhs.uk/information-about-patients/
[SITE SPECIFIC DETAILS for centres other than Cambridge]

[For Cambridge University Hospitals NHS Foundation Trust, please visit: *https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information,* or email the Data Protection Officer at: *gdpr.enquiries@addenbrookes.nhs.uk*

Or by asking one of the research team using the contact details on the back of this leaflet.
OR SITE-SPECIFIC INFO]

Part 4 - What should I do if something goes wrong?

If you have any concern about any aspect of this study, please contact us (the research team) and we will do our best to answer your questions – our contact details can be found at the end of this information sheet.

In the event that something does go wrong, you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against [Cambridge University Hospital Foundation NHS Trust or local trust] and the University of Cambridge but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the clinical trial caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the trial, but no-one has acted negligently.

[The University of Cambridge or local trust] will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the clinical trial.

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

If you remain unhappy and wish to complain formally or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your hospital.

Patient Liaison and Advice Service (PALS) Contact Details:
[Tel: (01223) 216756 Email: pals@addenbrookes.nhs.uk OR SITE PALS CONTACT DETAILS]

Part 5 – Contact us.

If you or someone on your behalf needs to contact the research team, you can do so as follows:

Phone: [Contact us using the following number during working hours (Monday to Friday 9.30 am – 5 pm.) 01223 216446

If we miss your call or if you call outside normal office hours, there is an answering machine on this number. If you leave a message, we will respond to you at the earliest opportunity OR SITE SPECIFIC INFO]

Email: [cuh.precision-hboc.nhs.net OR US site project email address]

Address:
Precision HBOC
[Professor Marc Tischkowitz
Department of Medical Genetics
Box 134, Addenbrookes Treatment Centre OR SITE SPECIFIC ADDRESS]