PROSPECTIVE STUDY OF 3D MAMMOGRAPHY (TOMOSYNTHESIS) IN BREAST CANCER SCREENING

P A R T I C I P A N T I N F O R M A T I O N

We would like you to take part in our research study of 3D mammography (tomosynthesis) in breast cancer screening.

We are doing research into a new way to screen for breast cancer, using 3D technology.
This leaflet explains why the research is being done and what it would involve if you agree to help.

If you have any questions once you have read this leaflet, one of our clinical research team will be happy to discuss the project with you and explain anything you are not sure about.

Why are we doing this study?

We want to find out more about the effectiveness and cost of using 3D mammography for routine screening in the UK.

The National Breast Cancer Screening
Programme routinely uses
2D mammography (2DDM)

Its accuracy is limited because of the overlapping of normal tissues

- this means that some cancers may not be seen

and

- overlapping of normal tissues may cause an appearance which looks suspicious for cancer, leading to recall for further tests and the associated extra stress and worry

3D mammography uses a computer to provide three-dimensional images.

The equipment used in this study has been shown in studies conducted in the UK and abroad to produce images which improve the accuracy of mammography.

This has two benefits:
- improved detection of small cancers
- fewer unnecessary recalls for women who do not have cancer

How is the study organised?

The study is being carried out in breast screening centres in England. We aim to recruit up to 100,000 women aged 49-71 years who are attending for routine screening.
Women who agree to participate in the study will undergo either standard 2D mammography or 3D mammography. We will then compare the results between the two groups in order to assess the effect of 3D mammography on both cancer detection and 'false alarm' recalls, and the cost of 3D screening compared to standard mammography.

The results of the study will be used to decide whether to implement 3D mammography for routine screening. If it is decided to introduce 3D mammography for routine screening, this will be phased in over a period.

What will taking part involve?

If you agree to take part in the study, you will be given this information sheet to keep and asked to sign a consent form.

You will be offered screening with either standard 2D mammography or 3D mammography – a computerized randomization process will determine which test you have.

The mammogram images will be viewed by two film readers who have undergone specialist training in the interpretation of both standard and 3D mammograms. You will be sent a letter informing you of the outcome of your mammography screening within three weeks of your visit.

How does a 3D mammogram differ from a 2D mammogram?

In both cases, the radiographer will take two x-rays of each breast: one from the side and one from above. For 3D mammography, the breast remains compressed for approximately 8 seconds longer for each view.

Letting us use some of your data:

We will also ask for your permission to access any data that might be held about you on the National Cancer Registration and Analysis Service (NCRAS) if you do develop breast cancer in the future. You may withdraw your consent at any time should you no longer wish us to access this data.

Further information about keeping your data safe and confidential can be found on page X below.

Do I have to take part?

No, it is entirely up to you to decide whether to participate in the study.

You are free to withdraw from the study at any time without giving a reason. If you decide not to take part in the study or to withdraw from the study, it will not affect the standard of care you receive.

If you decide not to take part, you will be offered standard 2D mammography screening as normal.

What are the possible benefits of taking part?

We think that 3D mammography may be better than standard 2D mammography at detecting very small or subtle cancers.

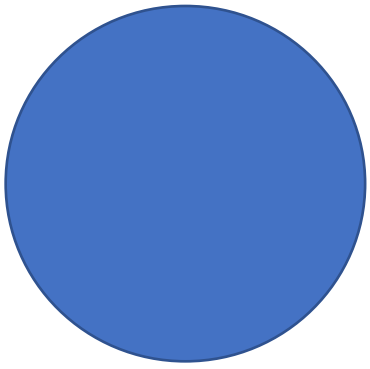
It may also mean that you are less likely to be recalled for further tests unnecessarily.

What are the possible disadvantages of taking part?

- Radiation

X-ray mammography involves the use of a small dose of ionizing radiation. In this study, a 3D mammogram involves slightly more radiation than a standard 2D mammogram.
Our radiation experts do not consider this to be a significant risk to health.

2.1 mSv = amount of normal background ionizing radiation received per year by a person living in the UK
mSv = millisievert, a measure of ionizing radiation



0.5 mSv = amount of ionizing radiation for a standard 2D mammogram

0.6 mSv = amount of ionizing radiation for a 3D mammogram

Study Data

What information do we want to access if you give your consent?

The National Cancer Registration and Analysis Service (NCRAS) is responsible for cancer registration in England and collects information in all patients with diagnosed cancer.
This information includes name, address, age, sex, and date of birth as well as detailed data about the type of cancer and the treatment the patient receives. This data is also linked to routine hospital records (Hospital Episode Statistics) about when you attend a hospital clinic, are admitted into hospital or go to A&E. The research team need to access this data to determine what treatment you have had and to measure the cost of your care.

In order for the research team to access the information held about you by the cancer registry, we need your permission to share your NHS number and your date of birth with the Cancer Registry to identify you.

Keeping your data safe and confidential.

The transfer of this information will be subject to strict confidentiality policies. The cancer registry will use your NHS number and date of birth to identify if details about you are recorded by the cancer registry and where there is, send this information back to us in order to provide us with information on your health status.

This data will be stored on a secure server at the Royal Surrey County Hospital and will be held and used in accordance with the new GDPR regulation. The data will not be shared with any other parties. You may withdraw your consent at any time should you no longer wish us to access this data.

What will happen to the images obtained during the study?

An anonymised set of your images will be stored on a central trial image database and may be used for further research looking at how 3D scans might be used in routine screening.

What is the timescale of the study and when will results be available?

The trial is being conducted over 7 years. Results will be presented and published during the course of the study and will be made available on the trial website.

Who will know that you are taking part in the study?

Any information, which is collected, about you during the course of the study will be kept strictly confidential. We will only use your name, date of birth and NHS number (with your permission) to allow access to data on you held by the National Cancer Registration and Analysis Service (NCRAS). Identifiable data will not be shared with anyone else and will be removed prior to any analysis by the research team. The relevant section of your medical notes and data collected during the study may be looked at by members of the
Research team or individuals from the regulatory bodies or from King's College
Hospital NHS Foundation Trust, where it is relevant to your participation in this research.

Using research data in the future:

Data collected by the research team will be securely and anonymously stored to enable use in other ethically approved research projects in the future.

This anonymized data may also be transferred and used by other organisations for commercial product development. Data provided by NCRAS will be destroyed on completion of the analysis of the study. Participants are free to request the destruction of any data held on them at any time.

What will happen to the results of the study?

The results of the research will be used to inform how 3D mammography may be used in routine screening. The results of the research will also be shared with the study participants and the public via the study website and relevant charities.

All study participant data will be anonymous.

Who has reviewed the study?

The study has undergone external review by experts, and patient and public representatives as part of the King's Research and Development protocol.

The study has been approved by the London – Dulwich Research Ethics Committee.

The study is sponsored by King's College Hospital NHS Trust and funded by Hologic Inc. Hologic are the first manufacturers to develop this 3D tomosynthesis technique that is accepted for use in the NHS breast screening programme.

The study has been endorsed by NHS screening programme.

Patient Advice and Liaison Service (PALS)

If you have any concerns regarding the care, you have received, or as an initial point of contact if you have a complaint, please contact the Patient Advisory Liaison Service (PALS).

PALS is a service that offers support, information and assistance to patients, relatives and visitors. They can also provide help and advice if you have a concern or complaint that staff have not been able to resolve for you. The PALS office is located King's College Hospital, staff will be happy to direct you:

Email: kch-tr.PALS@nhs.net

In the event that something does go wrong and 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 King's College Hospital NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Can I obtain further information about this study?

We hope that you have found the information in this leaflet helpful. If you would like further information to enable you to decide whether to participate in the study, please visit our trial website at
www.prospectstrial.org

In line with the national data guardian opt out; your personal details have not been shared with the research team. This generic information sheet has been included to invite you to participate in research.

Thank you for taking time to read this information sheet

Transparency requirements under the General Data Protection Regulation

King's College Hospital NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We 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 we are responsible for looking after your information and using it properly. King's College Hospital NHS Foundation Trust will keep identifiable information about you for 10 years after the study has finished.

As an NHS organisation, we use personally-identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Your rights 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.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe, we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). You can find out more about how we use your information at www.prospectstrial.org or by contacting our Data Protection Officer Nick Okane- Murphy at nick.murphy-okane@nhs.net.

King's College Hospital NHS Foundation Trust will collect information from your medical records for this research study in accordance with our instructions.

King's College Hospital NHS Foundation Trust will keep your name, NHS number, screening number and contact details confidential and will use this information as needed and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from King's College Hospital NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. King's College Hospital NHS Foundation Trust will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in relevant aspects of health or care, and could be combined with information about you from other sources held by researchers, the NHS or NCRAS (Please see page 5).

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.