King's College Hospital
NHS Foundation Trust

PROSPECTS

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

PARTICIPANT INFORMATION

V3 01.09.2022 IRAS Number 199080

We would like you to take part in our research study, **although joining the study is entirely up to you.**

This booklet explains why the research is being done and what it would involve for you.

If you have any questions, you will have an opportunity to ask one of the clinical research team before you decide whether to participate.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we provide more detailed information about the way the study is conducted.

What is the purpose of the PROSPECTS study?

Screening x-ray mammography is performed to detect breast cancers when they are small and before a lump has formed.

The current standard screening mammogram (2DDM) is a two dimensional image and its accuracy is limited because normal tissues overlap – this means that some cancers may not be seen. Conversely, normal overlapping 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 information which overcomes some of the problems caused by the appearance of normal overlapping tissue on standard mammograms. Some European studies have shown that 3D mammography finds more small cancers than standard mammography and may result in fewer unnecessary recalls for further tests.

The purpose of this study is to measure the effectiveness and cost of 3D mammography in routine screening in the UK.

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

Design of the study

The study is being carried out in eight screening centres in England.

The study is being carried out in eight screening centres in England. The study aims to recruit 100,000 women aged 50-70 years who are attending for routine screening. 50,000 will undergo standard mammography and 50,000 will undergo 3D mammography.

In the original trial design, women in the 3D mammography group would undergo both 3D mammography and standard 2D mammography. Results of recent studies show that a 'synthetic 2D' mammogram is as accurate as a standard 2D mammogram when combined with 3D mammography. Therefore, women undergoing 3D mammography will not in future undergo standard 2D 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 compared to standard mammography. The results of the trial will be used to decide whether to implement 3D mammography for routine screening. If it is decided to introduce tomosynthesis for routine screening, this would be phased in over a period of time.

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Do I have to take part?

No. It is entirely up to you whether you wish to take part 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 will happen to me if I agree to take part?

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 undergo standard mammography or 3D mammography screening according to the study randomisation process.

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The radiographer will take two x-rays of each breast; one from the side and one from above. The breast remains compressed for approximately 8 more seconds for each view. 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.

The National Cancer Registration and Analysis Service (NCRAS) is responsible for cancer registration in England and collects information in all patients with diagnosed cancer. As a cancer registry, NCRAS collects information on over 300,000 cases of cancer each year, including patient details (including their name, address, age, sex, and date of birth), as well as detailed data about the type of cancer, how advanced it is 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.

We would like to ask for your permission to access any data that might be held about you if you do develop breast cancer in the future. It will also allow us to estimate the cost of any treatment you might receive.

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 (or equivalent number in the devolved nations) and your date of birth with the cancer registry to identify you. 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 are the **possible benefits** of taking part?

Tomosynthesis may be better than standard 2D mammography at detecting very small or subtle cancers.

Tomosynthesis may also reduce 'false alarm' recalls

What will happen to the images obtained during the study?

Your images will be securely stored on a hospital computer system as part of your medical records. An anonymised set of your images will be stored on a central trial image database and will be used for further research. These studies will provide information on how this technology might be implemented for routine screening.

What is the trial **timescale** and when will results be available?

The trial will be conducted over seven years. This will allow for two rounds of screening and will allow sufficient time for collection of the screening results. Trial results will be presented and published during the course of the study and will be made available on the trial website. Initial results will be available 18-24 months following the start of recruitment.

Possible disadvantages and risks of taking part in the study

Radiation

X-ray mammography involves the use of a small dose of radiation. In this study the 3D mammography involves roughly 20% more radiation than a standard 2D mammogram. This has been considered by our radiation experts and is not considered to be a significant risk to health.

The radiation dose of a mammogram is approximately equivalent to three months of the normal background radiation we are all exposed to. The estimated natural lifetime risk of being diagnosed with breast cancer in the UK is 1 in 7.

If you undergo 3D mammography as part of the trial then there is an additional risk of causing breast cancer of 1 in 150,000, which is extremely small compared to the natural risk.

Thank You

We gratefully acknowledge your support in participating in this study, the results of which will be used to enable the NHS Screening Programme to decide whether and how to implement tomosynthesis for routine screening in women aged 50-70 years.

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:

Tel: 020 3299 3601

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).

Will my taking part in the study be kept **confidential**?

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. 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 anonymised 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 Trial. 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 information from the study will be analysed and submitted for presentation at one or more national or international medical meetings and submitted for publication in a medical journal.

The results of the research will be used to inform how tomosynthesis might be used in routine screening. The results of the research will also be disseminated to Trial participants and the public via the Trial website and relevant charities. All Trial participant data will be anonymised.

Who has **reviewed** the study?

This study has undergone independent external review as part of the King's Research and Development protocol, and has been approved by the London – Dulwich Research Ethics Committee.

This study is sponsored by King's College Hospital NHS Foundation 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.

This study has been endorsed by NHS screening programmes.

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.

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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.