PROSPECTS

Prospective Randomised Evaluation of Digital Breast Tomosynthesis (DBT) Plus Standard 2D Digital Mammography (2DDM) or Synthetic 2D Mammography (S2D) Compared to Standard 2D Digital Mammography in Breast Cancer Screening

Participant Information Sheet

Invitation
We would like you to take part in our research study, although joining the study is entirely up to you. This sheet 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 contact 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 conduct of the study.

What is the purpose of the 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.

Tomosynthesis (DBT) is a new method of obtaining x-ray images of the breast which can be performed at the same time as the standard mammograms. It uses a computer to provide three dimensional information which overcomes some of the problems caused by the appearance of normal tissue on standard mammograms. Synthetic 2D mammogram images (S2D) are generated by a computer from the tomosynthesis images and look similar to a standard mammogram.
The purpose of this study is to measure the effect of tomosynthesis imaging on the accuracy of mammography and to assess the cost of implementing tomosynthesis imaging in routine screening practice. 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 seven screening centres in England and one screening centre in Wales. 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 standard mammography plus tomosynthesis. We will then compare the results between the two groups in order to assess the effect of tomosynthesis on the accuracy of mammography in both cancer detection and ‘false alarm’ recalls. The cost of implementation of tomosynthesis in routine screening will also be assessed. The results of the trial will be used to decide whether to implement tomosynthesis for routine screening. If it is decided to introduce tomosynthesis for routine screening, this would be phased in over a period of time.

Do I have to take part?

No. It is entirely up to you whether you wish to take part in the study. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. 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 undergo standard mammography or standard mammography plus tomosynthesis screening, according to the study randomisation process.

The tomosynthesis imaging is done at the same time as the standard mammogram. 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 screening and tomosynthesis 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) collects information on all patients with cancer in England (http://www.ncras.nhs.uk/). This data is linked to routine hospital records (Hospital Episode Statistics). The Office for Data Release, a part of Public Health England, is responsible for the secure sharing of this data. We would like to ask for your permission to access any data that might be held about you, if you do develop any cancers in the future, by the NCRAS, including your hospital records. We will use this data to help ensure we record any breast cancers diagnosed from women participating in this research study. It will also allow us to estimate the cost of any treatment you might receive on your breasts. To do this, we need your permission to use your name, DOB and NHS number to access this data. This information will be transferred ~~directly~~ securely from the ~~mammography clinic~~trial screening centre to the Office for Data Release ~~in encrypted form~~. They will use it to identify any matching records and return ~~the data~~them to us after removing any identifying data.

~~This data~~Data from the NCRAS will be stored on a secure server at the Royal Surrey County Hospital and will be held and used in keeping with the Data Protection Act, 1998. The data will not be shared with any other parties. You are free to participate in the trial without consenting for us to access this data and you may also withdraw your consent at any time should you no longer wish us to access this data.

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.

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. These anonymised images will be used for further research to measure the effects of tomosynthesis on the accuracy of mammography screening. These studies will provide information on how this technology might be implemented in routine NHS practice for the benefit of women attending for screening mammography.

Possible disadvantages and risks of taking part in the study
The tomosynthesis examination involves approximately 8 seconds of additional compression for each of the two views taken of each breast. Some women experience mild or moderate discomfort during compression of the breast for a mammogram.

Radiation
X-ray mammography involves the use of a small dose of radiation. Tomosynthesis involves an additional dose of radiation roughly equivalent to that of a standard mammogram. Participation in the study would be equivalent to having two mammograms in a row. This has been considered by our radiation protection advisors and is not considered to be a significant risk to health.
The radiation dose of a mammogram is approximately equivalent to eight months of the normal background radiation we are all exposed to. The additional risk of causing a breast cancer in women participating in the trial who undergo tomosynthesis and standard 2D mammography is estimated as 1 in 29,000.

False positive recalls ('False Alarm' recalls)
Data from most published studies show that the number of 'false alarm' recalls is reduced with tomosynthesis. However, it is possible that in a few cases a trial participant might be recalled for further tests and be found not to have cancer.

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 the need for 'false alarm' recalls.

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.

Harm
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).

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
The Patient Advice and Liaison Service (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 ——- ---------- —staff will be happy to direct you.

Tel:
Textphone:
Fax:

Counselling service
The counselling service offers free and confidential sessions to all —— inpatients, outpatients, their relatives and friends. If you would like to meet with one of our counsellors you can contact them ~~of~~ on _____~~--------~~, or extension~~--------~~within the hospital.

If you would like this leaflet in a different format or language please contact PALS on ---------

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 to allow access to data on you held by the National Cancer Data 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. 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 program.

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 _____ or phone the trial information helpline at_____.
Please note that our screening clinics are often very busy and there will not be sufficient time available at your screening appointment to discuss further questions about the trial.

Thank you for taking time to read this information sheet and considering taking part in the study.