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NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

CONTEND STUDY

(An assessment of the impact of **CONT**rast **EN**hance**D** Spectral Mammography (CESM) on patient management and comparison with MRI)

You are being invited to take part in a research study. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 - tells you the purpose of this study and what will happen to you if you take part.
Section 2 - gives you more detailed information about the conduct of the study.

Section 1: Purpose of the study and what will happen

1. **What is the purpose of the study?**
   This is a pilot study looking at a new way of imaging the breasts called Contrast Enhanced Spectral Mammography (CESM) and whether it can provide additional information to help with diagnosis. The study will compare the results from patients undergoing CESM in addition to standard care with those from patients undergoing standard care alone to see if those who have CESM are given their final diagnosis sooner.

2. **What is standard care?**
   Standard care may include further mammography, ultrasound, a clinical examination, magnetic resonance imaging (MRI) and biopsy dependent upon findings in each individual case. Results of any biopsies taken are discussed at a weekly multidisciplinary team meeting (MDT) where a decision is made regarding the next steps in patient care or diagnosis.

   CESM will be in addition to any procedure undertaken as standard care.

3. **Why have I been invited?**
   You have been invited to participate in this trial because you have been shown to have an area of suspicion in your breast and we aim to investigate whether CESM would be a suitable procedure to assist in your diagnosis.

   We plan to include 100 participants from this hospital.

4. **Do I have to take part?**

Participating in this trial is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, however you are still free to change your mind and leave the study at any time without giving a reason. If you chose not to participate or to leave the study, your future medical treatment and normal standard of care will not be affected in any way.

5. What will happen to me if I take part?

If you agree to participate in the study, you will be asked to sign the Informed Consent Form at the end of this document. You will be given a copy of this to take away and refer to later.

We put people into two groups – one group will receive standard care and the other will receive CESM in addition to standard care. You will be allocated one of the groups for this trial in a random way (by chance), much like flipping a coin. **You will have a 50% chance of receiving CESM in addition to standard care.**

Prior to CESM procedure

If you are put into the group who will undergo CESM in addition to standard care you will be asked to complete a short questionnaire (yes/no answers) about your health and any previous x-ray examinations with contrast media (dye). You will also need to have a finger-prick blood test so we can check how well your kidneys are working.

CSEM procedure

The aim is to carry out the procedure on the same day as your clinic visit. This will be dependent upon time, staff available and your own circumstances. If necessary an appointment will be made to carry out the procedure within the next week. There is no preparation required for the procedure. The equipment used and the positioning is exactly the same as for a routine mammogram.

You will be given an injection of contrast media (dye) into your arm. This is the same type of contrast media used routinely in CT scanning. Two minutes after the injection the radiographer will position you and take pictures in each of the four routine mammography positions.

From the injection of the contrast media the procedure should only take around 10 minutes. You will be asked to remain in the department for 15 minutes afterwards.

Following the procedure

If CESM identifies any additional area of suspicion in your breast, a core biopsy from that area will need to be taken in addition to one from the original area of suspicion. Once the biopsies have been performed you will return to standard care procedures.

6. What are the possible disadvantages and risks of taking part?

You may need to undergo the procedure at an additional hospital visit.

It is likely you may experience some bruising at the site of the injection. It is also possible that you may suffer an allergic reaction to the contrast media (dye). This contrast agent is the same agent used for all iodine based intravenous contrast used in the Radiology Department in the hospital.

After injection into an artery or vein, it is uncommon (1% risk = 1-10 in 1,0000) to experience pain and discomfort

Rare effects (0.1% risk=1-10 in 10,000) include diarrhoea, irregular heartbeat, kidney problems, cough, fever, general discomfort or dizziness

Very rare (0.01%=less than1in 10,000) include seizures (fits), clouding consciousness, disturbance of senses like touch, trembling, flushing, difficulty breathing including severe breathing difficulty due to fluid in your lungs ,short term brain disorders(encephalopathy), short term memory loss, coma and stupor or myocardial infarction .

Minor reactions, e.g. skin rashes, hives, itching, nausea, dizziness, runny nose, brief retching and /or vomiting; will be closely monitored by Breast Unit staff until symptoms have alleviated or further action is needed. Staff in the room will summon additional help – including a Radiologist - by means of alarmed pull cord.

Moderate reactions e.g. headache, persistent vomiting, wheezing, palpitations, facial swelling, raised blood pressure (hypertension), abdominal cramps; may require an injection of antihistamine and/or adrenaline. A pack of emergency drugs for this purpose will be kept in the room where the CESM procedure is carried out.

In the exceptional event of a serious reaction which has the potential to be life-threatening, e.g. difficulty breathing, chest pain, irregular heartbeat, collapse, seizure, cardiac arrest; staff will make an urgent call the hospital's emergency resuscitation team.

The CESM procedure involves an additional dose of radiation which is roughly equivalent to that received on a long haul flight to New Zealand or 20 chest x-rays.

7. What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this study. It is probable that undertaking the CESM procedure will help in the assessment of your breasts. Also, information collected as part of your participation in this study may benefit patients with suspected breast disease in the future.

8. Expenses & Payment?

You will not receive any payment for participating in this study and we are unable to reimburse any expenses incurred by your participation in this study.

Section 2: Study Conduct

9. What if new information becomes available?

Sometimes during the course of a study, new information becomes available which might affect your decision to continue participating in this study. Your study doctor will contact you to discuss the new information and whether you wish to continue participating in the study. If you still wish to continue on the study, you will be asked to sign a new Informed Consent Form.

The study sponsor, the regulatory authority or the study doctor may decide to stop the study at any time. If that happens we will tell you why the study has been stopped and arrange for appropriate care and treatment for you.

10. What if I decide I no longer wish to participate in the study?

You are free to withdraw from this study at any time without giving a reason and without affecting your future care or medical treatment. Any information already provided or results from tests already performed on you will not be used in the study.

The study doctor may also choose to withdraw you from the study if they feel it is in your best interests or if you have been unable to comply with the requirements of the study. Reasons for study withdrawal could include:

- You have experienced a serious side effect
- You are unable to complete the visits or study documentation as required

If you have experienced any serious side effects during the course of the study which require you to withdraw from the study, your study doctor will follow-up with you regarding your progress until the side effect has stabilised or resolved.

11. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this study you should speak to your study doctor who will do their best to answer your questions.

In the event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Addenbrookes Hospital or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).The University has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this.

If you wish to complain 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 Cambridge University Hospitals NHS Foundation Trust:

Patient Advice and Liaison Service, Box 53, Cambridge University Hospitals, Cambridge Biomedical Campus, Hills Road, Cambridge, CB2 0QQ
Tel: 01223 216 756
Email: pals@addenbrookes.nhs.uk

12. Will my taking part in this study be kept confidential?

All information collected about you as a result of your participation in the study will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence. You may ask to see your personal information at any time and correct any errors if necessary.

Once you have agreed to participate in this study you will be allocated a unique study number which will be used on all your study documentation. This number will be linked to your personal information; however you will only be identified by this unique number.

Data and images made available to GE Healthcare at the end of the study will be anonymised to comply with data protection and patient confidentiality.

We will need to inform your GP of your participation in this study so that any medical decisions made by your GP account for any treatment you are receiving as part of this study.

Authorised staff, who work for or with the sponsor of the study, the hospital R&D Department or the Regulatory Agency responsible for drug research may require access to your personal information and/or medical records to verify the data for this study and ensure that it is being conducted in accordance with UK law. All information will be treated in the strictest confidence during the review process.

13. What will happen to the results of the study?

The results of the study will be anonymous and you will not be able to be identified from any of the data produced. When the results of this study are available they may be published in peer reviewed medical journals and used for medical presentations and conferences. Results will also be made available to GE Healthcare.

If you would like to obtain a summary of the results please contact the Trial Manager who will be able to arrange this for you.

14. Who is organising (sponsoring) and funding the study?

This study is sponsored by Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge.
The study is being funded by GE Healthcare who are providing money and equipment. GE Healthcare will not be involved in data management or in the interpretation of results of the study.

15. Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by (NRES Committee East of England- Cambs and Herts REC)

16. Further information and contact details

For general information about the study and your participation during office hours:
Paula Willsher (Trial Manager/Coordinator)
Tel: 01223 348931
Email: paula.willsher@addenbrookes.nhs.uk

IN THE EVENT OF AN EMERGENCY PLEASE CONTACT:

During office hours 0900-1700:
Dr Matthew Wallis (Consultant Radiologist) or Dr Penny Moyle (Clinical Director) Tel: 01223 585992

Outside of office hours 1700-0900:
Please contact the Addenbrooke's Main Switchboard on 01223 245151 and ask to speak to the Senior Radiology Specialist Registrar on-call.

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INFORMED CONSENT FORM

Study Title: An assessment of the impact of Contrast Enhanced Spectral Mammography (CESM) on patient management and comparison with MRI (**CONTEND Study**)

Principal Investigator: Professor Fiona J. Gilbert

Participant Number:

	If you agree with each sentence below, please initial the box	**INITIALS**
1	I have read and understood the Participant Information Sheet version 4.0, dated 24.02.16, for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected	
3	I understand that sections of my medical notes or information related directly to my participation in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4	I give permission for my GP to be informed of my participation in this study and sent details of the CONTEND trial.	
5	I understand that the doctors in charge of this study may close the study, or stop my participation in it at any time without my consent.	
6	I agree to participate in this study	

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes.