TO BE PRINTED ON
HOSPITAL HEADED PAPER

Poetic

Trial of Perioperative Endocrine Therapy - Individualising Care (POETIC)

PATIENT INFORMATION SHEET

We are inviting you to take part in a clinical trial called **POETIC**. Part 1 of this information sheet is about this research and what taking part involves. Part 2 gives you further information about how the study is being carried out.

Before deciding whether to take part, please read it carefully and discuss it with other people if you wish. Please ask your doctor or nurse if there is anything you do not understand or if you want more information. Take your time to decide.

This study forms part of the National Cancer Research Network's portfolio of approved studies.
This research is funded by Cancer Research UK.

Non-biological centres

CANCER RESEARCH UK

Part 1: About the POETIC study

We want to see if a 4 week course of hormone-blocking drugs called aromatase inhibitors, started 2 weeks before breast cancer surgery, can improve the long term outlook for patients with breast cancer.
We also want to see if changes to cancer cells caused by these drugs allow us to predict which patients respond best to hormone-blocking drugs. Finding tests that allow us to see who responds best to these drugs will allow us to tailor cancer treatment more accurately for future patients.

Why am I being invited to take part?

You have passed the menopause and a core biopsy taken from your breast showed that you have early breast cancer.

What treatment is being tested?

We are testing drugs called aromatase inhibitors. These are effective and widely used after surgery to treat breast cancer patients who have passed the menopause and have a type of breast cancer made up of cells that are stimulated by female sex hormones. We call this hormone receptor positive, or ER positive for short. These drugs come in tablets that are taken once a day after surgery and help to reduce the risk of breast cancer coming back. We now want to see if taking an aromatase inhibitor for 2 weeks before and 2 weeks after surgery adds to the benefit of the standard hormone treatment you will have after surgery. Your hospital can choose between two very similar aromatase inhibitors called anastrozole and letrozole. Your doctor will be pleased to tell you which one your hospital uses.

What are the side effects of treatment?

As with any drug, aromatase inhibitors have side-effects. These are uncommon and usually mild, but no-one can predict whether you will have any of them. The main side effect is joint stiffness. Other less common side effects include tiredness, hot flushes, vaginal dryness or irritation, slight hair thinning, headache.

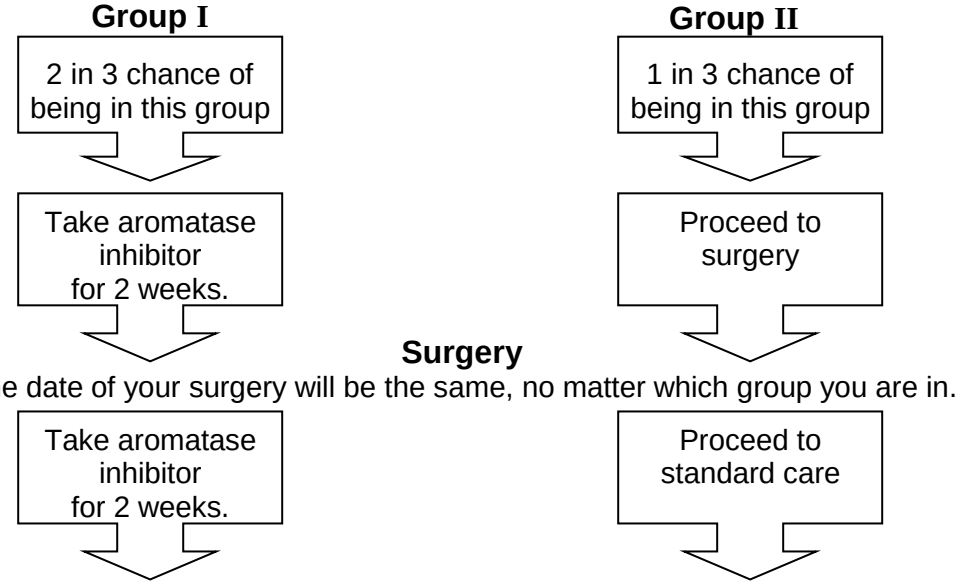
What are the alternatives to the treatment given in POETIC?

You will have your surgery in the normal way, and continue with a 5 year course of hormone treatment recommended by your doctor, which will probably include an aromatase inhibitor. You will be offered any other additional treatment your doctor thinks you should have. You will not be offered an aromatase inhibitor before your surgery outside the study.

What will happen to me if I take part?

If you agree to take part in the study, you will be allocated to one of 2 groups of patients. Patients in both groups will have surgery and standard care, but one group will also have an aromatase inhibitor for 2 weeks before and 2 weeks after their surgery.

It is important that the 2 groups of patients are as similar to each other as possible. This is because we need to be sure that if one group does better than the other group, it is because of the treatment, and not because the patients in the two groups are different from each other in some way. The only way to make sure that the groups are as similar as possible is by allocating patients to a group *at random.*



The study treatment lasts 4 weeks. We would like to take blood samples from you when you join the study, when you have your surgery and on one occasion after your surgery. We would also like to take a small sample of breast cancer tissue when you join the study and use some of the tissue that is taken away at surgery for this research. This is explained more fully below.

What will happen to the samples of Breast Cancer Tissue I donate?

Donating samples of breast cancer tissue is an essential part of this research.

If you agree to join the study, we need your permission to use tissue left over from the biopsy you had to diagnose your breast cancer. When you have breast surgery the rest of the breast cancer will be removed. Further samples from breast cancer tissue removed at surgery are needed for the POETIC study.

Your hospital will send these tissue samples to the Academic Biochemistry Department at the Royal Marsden Hospital in London. There, researchers will compare the breast cancer tissue samples to measure any changes in the breast cancer cells during the time that elapses between taking each of these samples. They will also compare the changes in tissue donated by patients who had an aromatase inhibitor with any changes in the tissue donated by patients who did not.

We would also like to take some blood samples from you when you enter the study, and again when you have your surgery and two weeks later. We will need just over two teaspoonfuls when you join the study, and about one teaspoonful at each of the two later times. As far as possible these will be taken at the same time as other routine blood tests. You may still join the study if you do not want to donate blood samples, but you will need to indicate this on the consent for you will be asked to sign.

Your blood sample will be processed and stored ready for laboratory research at the Department of Academic Biochemistry, Royal Marsden Hospital. One of these processes will be to extract, store and perform research on genetic material (DNA). This DNA will be used to help us discover whether a particular genetic make up leads to your type of breast cancer, and why some people respond better to aromatase inhibitor drugs than others.

Neither you nor your doctors will be told of the results of any additional research tests and they are unlikely to help your doctor treat your disease any differently or directly benefit you. We hope what is learnt from these studies could benefit patients with your type of breast cancer in the future.

If you do not want to donate blood, please initial the boxes on the consent form that say no to this part of the study. If you decide to take part, and later change your mind, you are free to withdraw your permission for researchers to use your tissue or blood sample at any time and your samples will be destroyed.

The table below shows what samples of blood and breast cancer tissue we would like to ask you to donate:

When we would like you to donate tissue	***The tissue we would like you to donate***	***How it will affect you***
When you join the study		These have already been taken and it will not affect you
Before surgery and before starting treatment with an aromatase inhibitor (if allocated)	2 blood samples	As far as possible, these will be taken at the same time as other blood samples
When you have surgery	2 or 3 small pieces of breast cancer tissue	These will be taken during surgery. You will not be aware of it.

	1 blood sample	As far as possible, this will be taken at the same time as other blood samples.
Your first visit after surgery (about 2 weeks later)	1 blood sample	As far as possible, these will be taken at the same time as other blood samples

The results of the laboratory tests will be coded and linked to the information we collect about your breast cancer and treatment in this study. It will not be reported back to you or your hospital doctor.

The samples of tissue will be given a code number, and stored securely in the care of the Institute of Cancer Research and the Royal Marsden hospital for up to 15 years. Any other additional research using your tissue will be scrutinized by an independent ethics committee before it is allowed to go ahead. If you do not want your breast cancer tissue used for any other future research, you can still enter the study, but should not initial the consent form giving permission to store your breast cancer tissue for any other future research.

What do I have to do?

If you are allocated to the group receiving an aromatase inhibitor, you will need to take this as described by your doctor, and have your surgery as normal. If you have any tablets left over, you will need to return them to your hospital.

If you are allocated to the group not receiving an aromatase inhibitor, you will have your surgery as normal.

We would like you to donate the blood and tissue samples described in this leaflet no matter which group you are in.

Do I have to take part?

It is up to you to decide whether or not to take part. If you agree to join you are still able to withdraw at any time without giving a reason. If you withdraw from the study it will not affect the standard of care you receive.

What are the benefits and risks of taking part?

There is no guarantee that you as an individual will benefit directly from taking part. We hope that the information we gain in the study will benefit patients who develop breast cancer in the future and that you will have helped by taking part.

If you have private medical insurance please check with the company before agreeing to take part that your medical insurance cover will not be affected.

What happens when the study treatment stops?

If you have been allocated to receive treatment, this will stop 2 weeks after your surgery. Whichever group you are in, the blood test taken at your first clinic visit after surgery will be your last study assessment. Your doctor will recommend a treatment plan based on your individual needs.

Taking part in the study will not affect the standard of care or the treatment you receive afterwards.

Your specialist is:

Contact telephone numbers:

Part 2: General information about how POETIC is conducted

Confidentiality

Your medical notes will be seen by authorised members of the research team at your hospital, so that they can collect information needed for the POETIC study, and also to check that it is correct. When you join the study, your name, date of birth, hospital number and NHS number will be passed to the Institute of Cancer Research Clinical Trials and Statistics Unit where the study is being coordinated. You will be given a unique registration number, which will be used together with your initials and date of birth on forms that the research staff send to the trials office. All information about you will be treated as strictly confidential and nothing that might identify you will be revealed to any third party.

All samples of tissue and blood you agree to donate will be sent to the Department of Academic Biochemistry at the Royal Marsden Hospital and identified using your name, date of birth, and a unique trial identification number, This is because samples of tissue/blood from different patients look exactly the same, and it is vitally important we do not get them mixed up. Once your tissue or blood samples arrive at the Royal Marsden, they will be processed and stored using a sample code. Your name will not be used in the laboratory, and your unique registration number will be used to link information from the laboratory research with other information about your treatment and progress sent by your hospital to the ICR-CTSU.

Research staff at the Clinical Trials Section at the Institute of Cancer Research will be contacting your hospital over the years to find out how you are getting on. Ideally we would like to do this for life, but patients sometimes change address and/or GP or lose touch with their hospital. If this happens we would like to use national records which are kept on everyone's health status to find out how you are. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth and NHS number (or Community Health Index and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the POETIC study. Please initial the consent form to show that we have your permission to do this.

Information from your medical records, about your treatment and disease will be sent to the Clinical Trials Section at the Institute of Cancer Research. Representatives from that organisation and/or regulatory bodies may wish to see your hospital or clinic records to make sure the information sent was correct. All information will be kept confidential.

What will happen to the results of the research study?

Independent experts will review the progress of the research, and the results will be published in a respected medical journal once we are sure they are reliable. No information that could identify you will be included and you will not be identified in any report or publication.

We will write the results in lay terms once they are available. Your hospital will be able to give you a copy.

What if something goes wrong?

It is unlikely that anything will go wrong with your treatment or care, but if you wish to complain about any aspect of the way you have been treated during the course of the study you can do so using the normal NHS complaints procedure.

Healthcare professionals working on Clinical Trials are covered by NHS Indemnity and if you are harmed by taking part in this study you may have grounds for a legal action but you may have to pay for it.

In the very unlikely event of you experiencing serious side effects from aromatase inhibitors whilst taking part in POETIC, full details would be reviewed carefully by the cancer specialist with overall responsibility for the study. These details will also be sent to the Medicines and Health Care Products Regulatory Agency (MHRA) who oversee the safety of people who take part in any research involving any drug treatment within the UK. We are required by law to do this.

What if I don't want to carry on with the study?

If you change your mind about having the treatment in this study, we would still like to collect information about your breast cancer, and use the samples of tissue you have donated. The information needed is routinely recorded in your medical records and you would not need to do anything. The samples of tissue would be transported, tested and stored, and you need do nothing further. If you do not want this to happen, please tell your hospital doctor or nurse and the samples you have donated will be destroyed.

Who is organising and funding the research?

POETIC is organised by leading cancer specialists at the Royal Marsden Hospital and Nottingham University Hospital, together with researchers at the Institute of Cancer Research in Sutton, Surrey.
Your doctor will not receive any personal financial payment if you take part.

This research is being paid for by Cancer Research UK and coordinated by The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU).

The National Health Service Research and Development Executive are paying for the extra nursing and administrative costs incurred by the hospitals.

Who reviewed this study?

POETIC has been approved by South East Research Ethics Committee on behalf of all hospitals throughout the UK. It has also been reviewed and approved by Cancer Research UK

What happens now?

Your doctor or nurse will be happy to answer any questions. Once you have reached your decision let your doctor or nurse know. You will be asked to sign a consent form and will be given a copy to keep together with this information sheet.

Further information

Macmillan is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. They have published useful booklets about (1) breast cancer (2) individual treatments and (3) clinical trials in general. You can contact one of their specialist cancer nurses on, 0808 808 00 00. For more information about the anastrozole and letrozole, you can also look on their Internet website. To do this go to http://www.macmillan.org.uk and click on cancer information, treatments, treatment types, hormonal therapies then individual hormone treatments, then the name of the drug you want to find out about.

Breast Cancer Care have a message board on their Internet website where you can read or add messages about deciding to take part and your experiences of treatment. To use it, go to www.breastcancercare.org.uk, select support for you and then click on discussion forums.

You can learn more about clinical trials on the Cancer Research UK's patient website (www.cancerhelp.org.uk).

Thank you for interest in our research.

Your specialist is:

Contact phone numbers: