Feasibility of International Breast cancer Intervention Study 3 (IBIS 3)

IRAS No: 165266

We invite you to take part in a research study

You are being invited to take part in the IBIS 3 Feasibility Study, a trial investigating the prevention of late cancer recurrence in breast cancer survivors following 5 years of hormone therapy.

Important things that you need to know

• To find out the best way to prevent late breast cancer returning, we are testing three types of medicines. These are metformin, zoledronic acid and a group of medicines called aromatase inhibitors (anastrozole, letrozole or exemestane). You will already have been treated with an aromatase inhibitor for your breast cancer and your doctor will discuss with you which aromatase inhibitor is the most suitable for you on the study.

• The medicines are given separately or in combination with each other resulting in eight different treatment groups, including a 'no continued treatment' group.

• If you join, you will be expected to attend a hospital clinic visit every 6 months. For all treatment groups the treatment will last for two years.

• Like all medicines, those used in this trial can have side effect but because these medicines are commonly used in other conditions, their side effects are well known and some people will experience no side effects at all.

• You can stop taking part in the study at any time, without giving a reason.

What is the purpose of the study?

This is a 'feasibility study', which simply means we want to determine the possibility of recruiting participants to a larger IBIS 3 study by monitoring recruitment rates over a 12 month period. The trial will examine whether certain drugs can prevent breast cancers, such as yours, from returning. Before we run the main IBIS 3 trial, we are conducting this smaller feasibility study to discover;

- Whether the women we would like to take part will actually want to join
- How long it will take us to recruit the number of women we need to be able to answer our research questions
- Whether there are any issues with taking the medications
- If we need to change anything about how the main trial will be organised

The study will investigate whether metformin and/or an aromatase inhibitor and/or zoledronic acid can be used effectively to prevent late breast cancer recurrence, either with each drug alone or in various combinations.

Why have I been asked to take part?

You have been chosen to take part in this study because you are postmenopausal, have had about 5 years of hormone treatment for breast cancer and now have no signs of cancer. Depending on the type and size of the cancer you had and whether the cancer had spread to the lymph nodes (tissues in the arm pits) there is a risk that the breast cancer may come back. You should discuss how likely it is that the cancer will return with your doctor.

Treatment as part of this research is for two years. However, should this study be successful you may be offered a third year of treatment followed by two more years of check-up appointments in clinic.

Do I have to take part?

It is your decision whether or not to take part. If you decide to accept our invitation to join, you will be referred to one of our breast cancer specialists who will explain the study to you in full details. You will be given the full patient information leaflet for you to read and discuss with family and friends.

What will happen to me if I take part?

You will be offered six monthly check ups during the treatment period, by one of many specialist breast care teams involved in the study. You will receive appropriate screening and health checks, and any problems or concerns you may have will be discussed.

Before you can join the trial, you will be asked some 'screening' questions to make sure you are suitable for the trial. If, after answering the questions, it turns out that you are not eligible, you will not be able to join the trial.

A small fasting blood sample will be taken to check your kidney function and the sugar levels in your blood will also be measured. You will be given a bone scan to check your bone health as well. If the test results indicate there may be a problem we will let you know if you cannot take part in this research, and may advise that you discuss the findings with your GP.

You will be assigned by chance to two years of treatment with one or more of the three drugs under study. Because there are eight possible treatment options, you have a 1 in 8 equal chance of being assigned to any of the options. This means that 7 out of 8 women will receive some form of treatment, whilst 1 woman in every 8 will receive the standard, i.e. no treatment.

Like all medication, these drugs will affect different people in different ways. There may be side effects, but this does not mean that all people taking these drugs will experience any or all of these.

What are the drugs that are being tested?

a) An aromatase inhibitor (anastrozole 1mg or letrozole 2.5mg or exemestane 25mg) is given as a daily tablet for 2 years

b) Metformin (with a starting dose of 500mg once a day gradually increasing to 850mg) is given as a twice daily tablet for 2 years

c) Zoledronic acid 4mg is given by injection intravenously (via vein) as a small infusion, which takes approximately 15-20 minutes, once every six months for 2 years. This is as an outpatient at your local hospital centre.

Aromatase Inhibitors (Anastrozole, Letrozole, Exemestane)

These drugs are already being used to treat breast cancer and you will probably have been treated with one for your breast cancer. The IBIS-II trial recently showed that they can reduce the risk of breast cancer occurring in the first place in women at high risk of the disease. They have been used in advanced breast cancer and have been found to be at least as effective as tamoxifen (standard treatment), but with fewer and less serious side effects.

Metformin

Metformin is the most commonly used drug in the treatment of diabetes. It is approved as a treatment for type II diabetes. Previous studies have shown that it can also inhibit the growth of cancer cells, including breast cancer.

Zoledronic acid

Zoledronic acid is used in the treatment of a number of different problems which affect bones. In osteoporosis, zoledronic acid helps by preventing further loss of bone by helping to rebuild lost bone. It is also used for strengthening the bone in some cancers. In Paget's disease, zoledronic acid works on bones to make them stronger and helps to prevent bone thickening.

Who is organising and funding the research?

Queen Mary University of London is organising this research and is the sponsor. Cancer Research UK (CRUK) and the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) are funding this study.

Contact for further information

If you have any questions about the study or you are interested in taking part please contact:

Jill Knox on 0207 882 3510 or send an email to ibis3patient@qmul.ac.uk

You can also visit the IBIS 3 trial website at:
http://www.ibis-trials.org