TO BE PRINTED ON HOSPITAL HEADED PAPER

PATIENT INFORMATION SHEET

SoFEA

Study of Faslodex

with or without concomitant Arimidex vs Exemestane

following progression on non-steroidal Aromatase inhibitors

Version 5: 1 December 2008

You are being invited to take part in a research study (clinical trial). Before you decide whether or not to take part it is important for you to understand why we are doing this research and what it involves. Please take time to read the following information carefully and discuss it with relatives, friends and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time deciding whether or not you wish to take part.

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

What is the purpose of this study?

The purpose is to see if Faslodex, which is a new hormone treatment given by injection (usually into muscles in the buttocks) is better in slowing down the progression of breast cancer than the standard hormone treatment (exemestane) which is used in most units. We also want to find out whether it is better to:

i use Faslodex on its own or
ii combine Faslodex with another hormone treatment called Arimidex.

Faslodex is given by monthly injection and other clinical trials have shown that Faslodex is a promising new treatment. In 2002 it was approved by the Food and Drug Administration (FDA) in the USA to treat advanced breast cancer.

Why am I being invited to take part?

You are invited to take part because your original breast cancer tumour contained 'markers' called oestrogen receptors, which means that hormone treatment is particularly suitable for you. You were therefore given either anastrozole (Arimidex) or letrozole (Femara). This study is for patients who have passed the menopause, and are no longer responding to these hormone treatments.

Breast cancer patients at hospitals all over the UK are being asked to take part, and about 750 patients will be included in the study. Hospitals in other European countries may also ask patients to take part.

How will my treatment be chosen?

Everyone who takes part in the SoFEA study will be allocated to one of three groups of patients with 250 patients in each group. Every patient has an equal chance of being in each of the groups. It is important that the three groups are as similar to each other as possible. This is because we need to be sure that if one group fares better than the others, it is because of the treatment, and not because the groups are different from each other in some way. The only way to make sure that the groups are as similar as possible is to allocate patients to the groups *at random,* which means by chance. A computer programme is used to make sure it is done properly. The three groups will be given the following treatment:

Group 1: Faslodex 250mg (5ml) given by injection into a muscle once a month PLUS one 1mg tablet of Arimidex to take by mouth once a day

Group 2: Faslodex 250mg (5ml) given by injection into a muscle once a month PLUS Placebo, a 'dummy' tablet that looks like Arimidex, to take by mouth once a day.

Group 3: One 25mg tablet of exemestane to take by mouth once a day.

Your specialist consultant or nurse will telephone the centre coordinating the study. They will be told if you are to have Faslodex or exemestane, and will be given a unique trial number for you.

If you are in one of the groups getting Faslodex, neither you nor your doctor will know if you are to have Arimidex or the placebo tablet. (A placebo is a dummy tablet that looks like the real thing but does not contain any active ingredient.) The reason for this is that if you knew which tablet you were taking it might influence how you felt. If the researchers knew which you were getting it might affect how they judged your responses to it.

If the doctor treating you needs to know in an emergency whether you are taking Arimidex or placebo, they can easily find out.

Do I have to take part?

No, participation in this study is entirely voluntary. If you do choose to take part you will be asked to sign a consent form and you will be given a copy to keep together with this information sheet. It is routine practice for your GP to be kept informed about your treatment and condition, and of the fact that you are taking part in a research study. We would therefore like your permission to do this. If you do not feel able to agree you will not be able to take part in the study and you will then be given the current standard treatment that is available.

What happens if I change my mind during the study?

If you agree to take part and then change your mind you do not have to give a reason and the standard of care you receive will not be affected. However, if this were to happen, we would like your permission to continue to collect information on your progress that is routinely recorded in your medical records. This is so that the overall quality of the study is not impaired.

When do I stop my current treatment?

If you decide to take part in the study your doctors will ask you to continue taking your current tablets (Arimidex or Femara) until you are ready to start your new treatment. It is important for the study that patients do not have a break from their previous treatment before they start the new treatment.

What will happen to me if I get the Faslodex treatment?

If you are in one of the treatment groups having Faslodex, you will have an injection every month into one buttock muscle apart from the first month when you will get a higher dose so that the correct levels in your body are reached quickly.

Therefore on the first day of your Faslodex treatment you will have two injections, one given into each buttock muscle. Two weeks later you will have a single injection into one of your buttocks and two weeks after this you will be given another single injection into the other buttock muscle. Thereafter you will have one injection only at monthly intervals.

What are the possible side effects?

Faslodex is a newer drug while Arimidex and exemestane have all been widely used in the past for patients with advanced breast cancer.
The side effects of the Faslodex injection itself are minor bruising, tenderness and/or redness at the injection site and you should avoid any pressure to where the injection has been given until the following day. Usually patients do not have much discomfort at the site.
Some of the other side effects or toxicities are described below. No one can predict whether you will have some, all or none of these, or how severe they may be. It is important that you tell your study doctor or research nurses about any problems you have at each hospital visit or you can telephone either of them between visits if you are concerned. Their numbers are at the end of this information sheet.

More common side effects of Faslodex can include hot flushes, and nausea. Occasionally other side effects can include tiredness, mild headache, vomiting, diarrhoea, loss of appetite, mild rash, or mild tract urinary infections.

The side effects of Arimidex may include general tiredness, hot flushes, vaginal bleeding, vaginal dryness or irritation, joint pain or stiffness, and loss of appetite. Sometimes patients experience mild hair thinning, headache, nausea, diarrhoea, or indigestion.

The side effects of combining Faslodex and Arimidex are not known, but we do not expect them to be any more severe than with either drug on its own. We would also not expect any greater risk of you developing blood clots with either Faslodex, Arimidex or with the combination of the two medications than with any of the treatments you have previously been prescribed.

The side effects of exemestane are hot flushes, nausea, fatigue, increased sweating and dizziness. Some patients experience headache, sleeplessness, abdominal pain and hair loss.

What will happen to me if I take part?

You will have a series of routine blood tests, x-rays, or CT scans to confirm that you are eligible to take part. These are normal routine standard practice for patients receiving hormone treatment and are not extra requirements for this study.

How often will I be seen in clinic?

Whichever treatment you receive you will be seen and examined in clinic every month for the first six months and then every three months after that when scans will be taken to see if you are responding to treatment. You will also have routine blood samples of approximately 10ml (2 teaspoons) taken. At each visit, you will be asked about your health and any other medications you are taking.

Additionally, if you are allocated to receive Faslodex, you will need to attend the clinic three times in the first month of treatment (the first day of your Faslodex treatment and then at two weekly intervals). Thereafter, clinic visits will continue monthly for the first six months after which you will be seen every three months.

What do I have to do?

You will need to continue taking the daily tablets that are prescribed for you and to attend clinic visits at the time intervals as already mentioned. If you receive the Faslodex treatment this will be given to you by injection.

At all clinic visits your health will be checked and you will be asked questions about the medications you are taking. Every 3 months you will have routine ultrasound or CT scans and blood tests.

How long will I continue to receive treatment?

Your study treatment will continue for as long as you are benefiting from it. If you want to stop treatment at any time you can.

What will happen to me when the treatment stops?

If at any time your doctor thinks it would be better for you to stop treatment s/he will talk to you about what the best options are at that time. However, even if the treatment does stop early you will be offered an alternative treatment that your doctor feels is appropriate for you and you will then be seen within routine clinics. However, further information about you will be relevant to our study and we would like to collect this from your doctor at regular intervals.

What are the possible benefits of taking part?

We cannot promise that you will directly benefit by taking part. Taking part may not help you personally, but you will be helping doctors to learn if this new treatment can benefit other people in the future.

What are the possible disadvantages and risks of taking part?

As with all new drug treatments there is always the possibility of unknown side effects.

You will also be asked to attend clinic monthly for the first six months (and one extra visit as mentioned if you are prescribed Faslodex)
If you take part in this trial you will be asked to make 4-5 extra hospital visits in total so that we can give you your treatment and monitor your care. Unfortunately, we will be unable to cover travel expenses for these extra visits.

Are there other ways of treating my condition?

If you decide not to take part, you will be offered a hormone treatment that you have not already tried. This could be tamoxifen or exemestane. As these treatments work in a different way to the treatment you have already been taking, they could be of benefit to you. Another form of treatment is chemotherapy. Your doctor will discuss these treatment options with you.

What about private cover?

If you have private medical insurance it is worth checking with your insurance company that taking part in the study will not affect your medical insurance.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the drug being studied. If this happens, your research doctor will tell you about it and ask if you want to continue in the study. If you decide to withdraw, your research doctor will arrange for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

If, in the light of new information your research doctor recommends that you withdraw from the study, s/he will explain the reasons for this.

What will happen to the results of the research study?

Independent experts will review the progress of the study, and as soon as there are reliable results, they will be published in a respected medical journal. After this they may also be reported in the national press. Your identity will not be revealed in any report or publication.

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.

If taking part harms you in any way, there are no special compensation arrangements, but the hospital in which you are treated would be liable for any negligence on the part of hospital staff.

Your progress will be watched closely and you will be offered whatever help is available to cope with any side effects.

Will my taking part in this study be kept confidential?

Yes. If you decide to take part information will be collected by authorised research staff either at the Institute of Cancer Research or the ISD Cancer Clinical Trials Team (Scotland). They will need to see your medical records so that they can collect and check information needed for the study therefore your name, date of birth and NHS number (or Community Health Index and/or hospital number in Scotland) will be passed to the them when you join the study. Outside the trial your unique trial number is used to make sure your identity is kept strictly confidential.

We 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 often 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 SoFEA trial. Please initial the consent form to show that we have your permission to do this.

Within the UK and the rest of the European Union, all personal information is subject to data protection laws. When you give information to someone (known as the data controller) they must make sure it is only used in ways for which you have given permission. Information from this study may also be passed on to regulatory authorities within and outside of Europe, where the data protection laws may not be as strict. If this happens your name will never be included.

How is the trial monitored for safety?

This study has been carefully planned by leading cancer specialists and approved by the South West Multicentre Research Ethics Committee.

As is standard practice for large randomised controlled trials like this one a monitoring committee of cancer experts (a statistician and two consultant oncologists) have been specifically appointed for this study and they will review its progress regularly.

Who is organising and funding the research?

This research study has been approved by the Clinical Trials Awards and Advisory Committee of Cancer Research UK and the Medical Research Council. It is being organised by the Clinical Trials & Statistics Unit at the Institute of Cancer Research (ICR), Sutton, Surrey, (which is a National Cancer Research Institute accredited Unit) and by ISD Cancer Clinical Trials Team (Edinburgh. Both of these organisations receive most of their money from the government and the major cancer charities. For this trial, AstraZeneca, the manufacturers of Faslodex and Arimidex, have provided an educational grant as an extra resource to the trials units to provide them with sufficient funds to conduct the study. AstraZeneca also provide Faslodex and Arimidex free of charge for patients taking part in this study.

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

Your doctor will not be paid for including you in this study.

Is there anything else I should know?

Your study doctor or research nurse will be happy to answer any questions you have about this study. You can telephone them on the numbers shown below, or speak to the doctor again when you come to the clinic.

Your legal rights are not affected by giving your consent to take part in this study.

CONTACT DETAILS

Your study doctor /Consultant is ..... **Telephone number** .....

Your research nurse is ..... **Telephone number** .....

Thank you for reading and considering taking part in this study