Centre number
MREC reference number 00/6/69
Version 6 created 03.11.06

Title of study: A prospective study of breast cancer treatment outcomes.

INFORMATION SHEET FOR PATIENTS

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask your breast care nurse or the national study co-ordinator if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information.

What is the purpose of the study?

Most breast cancer occurs by chance and usually with increasing age. Breast cancer is less common at young ages and this is why you have been asked to join this study. A small percentage of breast cancers arise because of a genetic predisposition (hereditary) These hereditary breast cancers are uncommon but may behave in a different way to cancers arising by chance (sporadic cancers). We are trying to learn more about any differences in the effect of treatment for hereditary compared to sporadic breast cancer.

Why have I been chosen?

All women in participating centers across the UK who have been diagnosed with breast cancer at 40 years of age or younger; and women who are known BRCA1 or BRCA2 gene carriers, diagnosed at 50 years of age or younger, are being invited to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part in the research study. You can take up to a year to decide. If you decide to take part you should keep this information sheet in a safe place and you will be asked to sign a consent form. You may withdraw from the study at any time without giving a reason and this will not affect your routine medical care in any way.

What would I have to do?

We would like you to fill in a questionnaire about your family history and a few other simple questions.
We will also ask your hospital doctors to answer some questions about your treatment and request an update on your progress from time to time from the hospital or your GP. Prior to treatment you will be asked to have your weight measured and recorded. This measurement along with your waist and hip measurement will be repeated one year after your breast cancer was first diagnosed by doctors / nurses in your clinic. You will be

contacted by your local Study Co-ordinator to arrange this at your convenience which is most likely to be at a routine follow-up appointment.
If you agree, you will be asked to provide blood samples, 3 x 10ml, (approximately three tablespoons) for future genetic analysis. In some cases a further blood sample of 3x 10ml, may be requested at a later date.
If you agree we will ask your doctor for small samples of the tissue removed at your operation to help us to understand why cancers sometimes behave in different ways.

Confidentiality
The information you supply and details about your treatment from your hospital records will be stored at the co-ordinating centre in Southampton, England. The data will be completely confidential and will not be disclosed to anyone, not even other members of your family or your doctor. We will inform your doctor that you have been enrolled in the study.

Are there any results from the blood tests?
No, there will be no individual results. Although genetic analysis will eventually be carried out towards the end of the study period this will be done in the research laboratory. We cannot give results from research tests as these tests are not carried out under the same rigorous quality assurance that applies in diagnostic genetics services. If you and your doctor feel a genetic test might be helpful because of a strong family history of cancer you can be referred to your nearest genetic centre. The national study co-ordinator would be happy to advise informally about whether this might be a helpful course of action and you could discuss this with your GP or your hospital specialist. If at any time you want to pursue formal genetic analysis we will be able to provide information regarding what testing has been completed to your local genetics service so that formal testing in the diagnostic laboratory may be easier.

What if new information becomes available?
The study plans to follow 3,000 women over 20 years. No individual results will be available directly to study participants at any time to protect confidentiality. The results of analyses on all participants together carried out at various times during the study will be made available to all participating hospital specialists and if at any time the results indicate that alternative or additional treatment would be appropriate your hospital specialist will be able to discuss this with you.

If I have any questions, whom can I ask?
Your local study co-ordinator is:-

The National study co-ordinator is:-
Professor Diana M Eccles
Consultant in Cancer Genetics
Wessex Clinical Genetics Service
Princess Ann Hospital

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