



Trial of Accelerated Adjuvant Chemotherapy with
Capecitabine in Early Breast Cancer

Cardiac function study

PATIENT INFORMATION SHEET

This study is approved by Cancer Research UK, who are providing financial support



You may remember joining the Trial of Accelerated Adjuvant Chemotherapy with Capecitabine in Early Breast Cancer (TACT2) a few years ago. A copy of the patient information sheet you received at the time is attached. We would now like to invite you to join an extra "sub-study" which looks at any possible long term side effects chemotherapy might have on the heart.

Chemotherapy is known to have a very small risk of causing heart damage, which is why you had a test to check heart function before you started chemotherapy treatment. In this sub-study we would like you to have 2 extra tests, either an echocardiogram (an ultrasound of your heart) or a MUGA scan which uses radiation. These tests will be done between 2.5 and 7 years after joining the trial and again at 10 to 14 years. A reminder letter will be sent to you at about 9-13 after joining the trial inviting you to return for a further test.

Small amounts of natural background radiation come from the earth and sky, and we are all exposed to this every day. If your hospital is one that uses MUGA scans, the total dose of radiation you will get from these extra tests is about the same as 10 years natural background radiation in the UK. The International Commission on Radiological Protection regards this as a low risk and you are unlikely to notice any effect on your health.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, the tests will either be done when you attend a regular check up, or you may need to attend two extra hospital visits to have the scans. You will be asked to sign a consent form and you will be given a copy to keep, together with this information sheet. Your GP will be told if you are taking part in this sub study, unless you specifically request that he/she is not told.

If you agree to join the cardiac sub-study you are free to withdraw at any time without giving a reason, this will not affect the standard of care you receive and will not affect the follow up you receive for the main TACT2 trial. You are of course free to withdraw from the main TACT2 trial also at any time, without giving a reason. However, if this were to happen, we would like permission for your hospital to send information on your progress to the clinical trials office. The information needed is routinely recorded in your medical records and you would not need to do anything. Collecting this information ensures that the overall quality of the research study is not impaired.

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 will benefit patients who develop breast cancer in the future. However, these tests will be able to show any early signs of a heart problem. If this happened you would be referred for specialist treatment.

What do I do now?

Your doctor or nurse will be happy to answer any questions over the telephone or when you next come to the clinic. Once you have reached your decision let your doctor or nurse know.

Your specialist is:

Contact phone numbers: