PARABLE

PROTON BEAM THERAPY IN PATIENTS WITH BREAST CANCER:

EVALUATING EARLY AND LATE EFFECTS

You will be receiving radiotherapy as part of your breast cancer treatment

The PARABLE study may be a possible option for you in the future

ICR The Institute of Cancer Research

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PARABLE: Introductory Patient Information Leaflet
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Why are we running the PARABLE trial?

Around 33,000 breast cancer patients/year need radiotherapy as part of their treatment. For around 500/year radiotherapy may be more difficult due to the need to treat lymph nodes near the breast-bone. A person's body shape can also make treatment difficult. This may increase the small risk of serious heart problems many years later.

Proton Beam Therapy (PBT) is a type of radiation therapy. It uses protons (high-energy charged particles) rather than x-rays to treat cancer. PBT may potentially reduce risks of side-effects in normal tissues such as the heart. **We want to compare PBT with radiotherapy (using x-rays) in breast cancer patients who may be at higher risk of side-effects from radiotherapy.**

We would like to see if PBT reduces the predicted very small risk of long-term serious heart problems, whilst not increasing other more common shorter term side-effects such as skin changes. PBT is provided by the NHS at The Christie NHS Foundation Trust in Manchester and University College Hospital in London. If you live outside Manchester or London and receive PBT as part of the study, it may mean being away from home for treatment if it is too far to travel daily. A family member, friend or carer can come with you and you will be supported by a team of doctors, nurses and other health professionals at the NHS PBT centre. If you do not live near the NHS PBT centre, arrangements will be in place to support accommodation requirements and travel from your home to the NHS accommodation. Further details will be provided if you are found to be eligible for the main study.

Is this trial suitable for me?

We do not yet know whether this trial is suitable for you. As part of your standard of care you will have a radiotherapy planning CT scan in your local centre to design your radiotherapy. Once you have had your planning scan, your local centre will be able to say if you are eligible to take part in PARABLE.

What happens if I am eligible and I enter PARABLE?

If you are found to be eligible for PARABLE and are interested in taking part, we will give you further information about the study. Within PARABLE you will receive either tailored radiotherapy 'tailored RT' (tailored RT delivered within PARABLE is the most targeted and modern radiotherapy available worldwide) or PBT. The choice as to which type of radiotherapy you receive is made at random, by a computer, at the time you enter the study. This process is called 'randomisation'.

Whichever group you are randomised to, everybody who takes part in the trial will receive the best possible care and regular monitoring by their clinical team.

Tailored RT

If you receive tailored RT you will receive 15 treatments of radiotherapy to the breast/chest wall and lymph nodes, once a day (weekdays), over 3 weeks. All treatment and follow up will take place at your local radiotherapy centre.

Proton Beam Therapy (PBT)

If you receive PBT you will receive 15 treatments of radiotherapy to the breast/chest wall and lymph nodes, once a day (weekdays), over 3 weeks. Treatment will take place at either The Christie NHS Foundation Trust in Manchester or University College Hospital in London. You will need to attend for a pre-treatment visit for radiotherapy planning and treatment. **You will require an additional CT planning scan at your PBT centre if you are in the proton beam group.** Once your radiotherapy is completed, all trial-related follow-up will be back at your local hospital/radiotherapy centre.

What happens if I am not eligible for PARABLE?

You will continue your current treatment and have your radiotherapy as planned at your local centre as per standard of care. This treatment will be just as effective in reducing your risk of cancer recurrence as any radiotherapy given in the PARABLE trial. In addition, being ineligible for PARABLE means that the cardiac risks from your standard radiotherapy plan are likely to be very low.

Thank you for taking the time to read this leaflet

For more information about the PARABLE study, please speak to a member of your hospital breast radiotherapy or oncology team.

Contact details for the team responsible for PARABLE at this site:

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PARABLE is sponsored and co-ordinated by The Institute of Cancer Research. It has been approved by the National Institute for Health Research (NIHR) – Efficacy and Mechanism Evaluation (EME) Programme, Health Research Authority (HRA), the West of Scotland Research Ethics Service and the study Sponsor's Committee for Clinical Research.