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TARGIT R: TARGeted Intraoperative radioTherapy (TARGIT) Registry database

Submission date 24/04/2013	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/05/2013	**Overall study status** Ongoing	
Last Edited 05/07/2022	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
We have set up a database of patients with early breast cancer who are being treated with radiotherapy during surgery. More than 2000 women have already received this treatment in clinical trials. We want to monitor the health status of women who receive this treatment outside of a clinical trial, especially those who might not have been eligible for the original clinical trials. Our aim is to monitor the long-term effectiveness and safety of the technique.

Who can participate?
Women over the age of 45 with early breast cancer where the doctors looking after them feel that the treatment is suitable. There is no upper age limit. This study will be made available to all hospitals in the UK, Europe and elsewhere, but they must have the special equipment in place.

What does the study involve?
Women selected for this treatment will be asked to read an information leaflet and sign a consent form. If you wish to participate, surgery and radiotherapy will be performed at the same time. Information about the patient, the breast cancer and the treatment will then be sent to a central office in University College London. The data will be kept securely, and any information that might identify an individual (such as name) will not be released to anyone outside of the study team. We will ask for updates on the patients' health status about once per year for at least 10 years.

What are the possible benefits and risks of participating?
Your doctor will explain to you the risks and benefits of radiotherapy. One of the benefits of having the radiotherapy during surgery is that you do not have to attend the radiotherapy centre for treatment every day for several weeks. However, some hospitals might have a rule that only women taking part in the study can be offered the treatment. Women can ask to be withdrawn from the study at any time.

Where is the study run from?
University College London in collaboration with Royal Free Hospital, London, The London Clinic, and Royal Hampshire County Hospital (UK)

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start mid-2013 and will continue to at least July 2022. Data will be collected from participating women for at least 10 years.

Who is funding the study?
Initial funding has been provided by a charity at the Royal Free Hospital in London. If the study proceeds satisfactorily, then further funding will be sought. Data collected during the study will be maintained on the secure database in University College London.

Who is the main contact?
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Study website
https://www.ucl.ac.uk/surgery/research/surgical-interventional-trials-unit-situ/situ-trials-0

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02947425

Secondary identifying numbers
2.0

Study information

Scientific Title
TARGIT R: Initiation and maintenance of a registry database of patients treated with TARGeted Intraoperative radiation Therapy using intrabeam (TARGIT) following breast conserving surgery for early breast cancer

Acronym
TARGIT R

Study objectives
Early data from our HTA funded randomised controlled trial (TARGIT A) registered under ISRCTN34086741 (http://www.controlled-trials.com/ISRCTN34086741) has shown that treatment with targeted intraoperative radiation therapy using Intrabeam (TARGIT) following breast conserving surgery for early breast cancer is non inferior to conventional external beam radiotherapy, in terms of efficacy and safety.

In parallel with this study we gathered evidence that the technique can also be used in patients who did not meet the eligibility criteria; for example, those with collagen vascular disease where external beam radiotherapy is contraindicated. The TARGIT R study will have wider patient selection criteria and is designed to not only include patients who would have been eligible for recruitment in TARGIT A, but also patients with breast cancer in special circumstances, for example: patients with systemic lupus erythematosus, scleroderma, motor neurone disease, Parkinson's disease, ankylosing spondylitis, morbid obesity and cardiovascular or severe respiratory disease and patients who had received previous external beam radiotherapy (EBRT) (mantle radiotherapy for treatment of lymphoma or developed 2nd primary cancer in the same breast) and refuse mastectomy. With all patients, it is essential that cases are discussed at the local multidisciplinary team (MDT) meeting and if approved, TARGIT can be considered for these patients in a clinical research setting (TARGIT R). This will enable us to gain an understanding of how the technique works in these complex scenarios, and will provide valuable information to clinicians and important data for incorporation into NICE guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Islington, 08/09/2014, ref: 14/LO/1452

Study design
Prospective observational multi-site outcome study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Early breast cancer suitable for breast conserving surgery

Interventions
Registration of patients selected for this treatment; collecting data regarding safety and toxicity on patients who have had treatment with TARGIT.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outcomes will be measured over short and long terms. Outcome measures will include effectiveness and safety, assessed in various cohorts of patients. Core outcomes will be used for effectiveness. In addition, 'true recurrence' (basically, ipsilateral breast tumor recurrence at the same site as the original primary) will be used as defined by Recht. Safety outcomes will be based on Common Toxicity Criteria.

Secondary outcome measures
Budget impact analysis of IORT in subgroups of patients will be assessed. This amounts to using cost data to calculate the mean incremental (or extra) cost per person treated using intraoperative radiotherapy (IORT) versus external beam radiotherapy (EBRT) and mastectomies (where IORT could have been given instead) and then multiplying this by the total patients eligible nationally for IORT, to calculate the total expected budget impact on the NHS if IORT in these subgroups was rolled out nationally.

Overall study start date
01/07/2013

Completion date
31/07/2032

Eligibility

Key inclusion criteria
1. Recommended treatment by Multi-Disciplinary Team (MDT)
2. Consent has been obtained for data to be collected

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
The aim is to include all women treated with the technique who are not otherwise participating in a randomised controlled trial.

Key exclusion criteria
Under 18 years of age

Date of first enrolment
01/07/2013

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
Australia

Canada

Denmark

England

France

Germany

Italy

Norway

Poland

Switzerland

United Kingdom

United States of America

Study participating centre
Royal Free London Foundation Trust
London
United Kingdom
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/jro

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Royal Free Charity (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No