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TARGIT: TARGeted Intraoperative radioTherapy versus postoperative radiotherapy

Submission date	Recruitment status	[_] Prospectively registered
21/07/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-radiotherapy-during-surgery-for-early-stage-breast-cancer

Study website
http://www.targittrial.org/TARGIT/indextargit1.shtm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00983684

Secondary identifying numbers
HTA 07/60/49

Study information

Scientific Title
TARGIT: a randomised controlled trial to compare targeted intra-operative radiotherapy with conventional post-operative radiotherapy after conservative breast surgery for women with early stage breast cancer

Acronym
TARGIT

Study objectives
Current hypothesis as of 17/05/2010:
TARGIT is an international randomised clinical trial designed to test the hypothesis that the strategy of delivering a single dose of targeted intraoperative radiotherapy (IORT) in patients eligible for breast conserving therapy (with the addition of whole breast radiotherapy in those patients at high risk of recurrence elsewhere in the breast [e.g. lobular carcinomas and extensive intraductal component]) is equivalent to a conventional course of post-operative external beam radiotherapy (EBRT). The primary endpoints are local and loco-regional recurrence rates. It is a pragmatic trial in which each participating centre has the option to define more restrictive entry criteria than in the core protocol. Only centres with access to the Intrabeam® (Carl Zeiss) enter patients into the trial. Eligible patients are those with tumours of good prognosis suitable for breast conserving surgery. After giving consent patients are randomised to either IORT or to EBRT. They may receive any other adjuvant treatments as deemed necessary, except for neoadjuvant therapy. The protocol requires that patients be followed at six monthly intervals for five years and then annually.

Previous hypothesis:
The TARGIT trial is an international randomized controlled clinical trial comparing single-day targeted intraoperative radiotherapy to conventional postoperative radiotherapy for women with early stage invasive breast cancer treatable with lumpectomy. Currently, single-day targeted intraoperative radiotherapy is investigational, which means that this treatment is still under evaluation as a treatment for breast cancer. Although small studies indicate that single-day targeted intraoperative radiotherapy is as safe and effective as conventional postoperative radiotherapy for certain patients, a long-term, scientific, head-to-head comparison of the two treatments is needed to determine if they are truly equal. This is the purpose of the TARGIT trial.

Further reading:
More details, including a list of publications, reviews, publicitiy articles, case reports and presentations, can be found at: http://www.dundee.ac.uk/surgery/targit/targitpapers.htm

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/076049
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0007/51892/PRO-07-60-49.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)
University College Hospitals Ethics Committee, 25/02/2000, ref: MREC No. 99/0307

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.dundee.ac.uk/surgery/targit/Dundee%20SIS%20Single%20Procedure%20v2.pdf; http://www.dundee.ac.uk/surgery/targit/Dundee%20SIS%20Subsequent%20Procedure%20v2.pdf

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Current interventions as of 17/05/2010:
Intrabeam device: a dose of 20 Gy at the surface of the applicator or 6 Gy at 1 cm (in water) is prescribed by the radiation oncologist and delivered to the breast tissue. This takes approximately 30 minutes, depending on the size of the applicator.
Post-operative radiotherapy: all patients randomised to receive conventional radiotherapy within this trial should be treated in accordance with a pre-specified policy. Dosage should only be applied to the breast; axillary, supra-clavicular and internal mammary nodes should not generally be irradiated by discrete fields.

Previous interventions:
Use of the Intrabeam device to deliver intra-operative radiotherapy after wide local excision (WLE) as compared to delivery of standard external beam radiotherapy (EBRT).
In the TARGIT trial, half of the participants will receive single-day targeted intraoperative radiotherapy given at the time of surgery. The other half will receive conventional postoperative radiotherapy given over a 6-7 week period beginning after surgery.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Added 17/05/2010:
Local relapse within the treated breast

Secondary outcome measures
Added 17/05/2010:
1. Site of relapse within the breast
2. Relapse-free survival and overall survival
3. Local toxicity/morbidity

Overall study start date
01/03/2000

Completion date
31/03/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/05/2010:
1. Age 45 years or older
2. Operable invasive breast cancer (T1 and small T2, N0-1, M0) confirmed by cytological or histological examination
3. Suitable for breast conserving surgery
4. Previously diagnosed and treated contralateral breast cancer may be entered but will be randomised to a separate stratum
5. Available for regular follow-up for at least 10 years
Note: Individual centres may wish to restrict entry to a more exactly defined subset of patients, in which case only patients with these characteristics may be entered by that particular centre. For example, centres may decide at outset to recruit only women over 50 or even over 65 years of age. Such policies must be pre-defined in writing and approved by the International Steering Committee.

Previous inclusion criteria:
Eligible patients are those with tumours of good prognosis suitable for breast conserving surgery.

Prior to joining the study, women must meet with the study investigators to determine if they qualify for the TARGIT trial. This evaluation will include a physical examination, review of mammograms and ultrasounds, and review of pathology results. Additional radiology studies (mammograms, ultrasounds, and/or breast MRI) may also be requested prior to determining eligibility for the study.

In order to participate in the TARGIT trial, the following criteria must be met:
1. Age 40 or older
2. Invasive (also called infiltrating) breast cancer
3. Breast cancer measuring 3 cm (1-1/8 in) or less
4. Breast cancer treatable with lumpectomy
5. Capable of receiving breast radiotherapy (not pregnant, no history of previous radiotherapy to the same breast, no connective tissue disorder)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3432

Total final enrolment
2298

Key exclusion criteria
Current exclusion criteria as of 17/05/2010:
1. More than one obvious cancer in the same breast as diagnosed by clinical examination, mammography or ultrasonography
2. Bilateral breast cancer at the time of diagnosis
3. Ipsilateral breast had a previous cancer and/or irradiation
4. Patients known to have BRCA2 gene mutations, but testing for gene mutations is not required
5. Lobular cancer or extensive intraductal component (EIC ≥25% of the tumour is intraductal) on core biopsy or initial pathology (if performed)
6. Patients undergoing primary medical treatment (hormones or chemotherapy) as initial treatment with neoadjuvant intent of reducing tumour size should be excluded; those given short duration (up to 4 weeks) systemic therapy can be included
7. Patients presenting with gross nodal disease, considered to be clinically malignant or proven cytologically or by scanning. In general, four or more positive nodes or extranodal spread are not suitable for TARGIT alone and should receive EBRT as well. However, individual centres may decide that anything more than micrometastasis should receive EBRT
8. Patients with any severe concomitant disease that may limit their life expectancy
9. Previous history of malignant disease does not preclude entry if the expectation of relapse-free survival at 10 years is 90% or greater
10. Any factor included as exclusion criterion in the local centre's Treatment Policy. This is particularly relevant to patients entered into the post-pathology stratum
11. No more than 30 days can have elapsed between last breast cancer surgery (not axillary) and entry into the trial for patients in the post-pathology stratification

Previous exclusion criteria:
1. Multiple areas of cancer within the breast
2. Cancer in both breasts
3. Diagnostic biopsy shows extensive non-invasive cancer (DCIS or Ductal Carcinoma in Situ)
4. Lymph nodes contain cancer metastasis

Date of first enrolment
01/03/2000

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Australia

Canada

Denmark

England

France

Germany

Italy

Norway

Poland

Switzerland

United Kingdom

United States of America

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UCL Medical School
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Sponsor information

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University College London (UK)

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Sponsor type

University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	01/08/2001		Yes	No
Other publications	discussion of operative technique	01/06/2002		Yes	No
Results article	Australian results	01/12/2004		Yes	No
Results article	German results	01/07/2005		Yes	No

Results article	German results on long-term toxicity	01/10/2006		Yes	No
Results article	results on recurrence rates	01/12/2006		Yes	No
Results article	international results	01/10/2007		Yes	No
Results article	environmental and social benefits results	09/05/2016		Yes	No
Results article	results	01/09/2016		Yes	No
Results article	long-term results	19/08/2020	24/08/2020	Yes	No
Results article	new insights results	01/05/2021	27/05/2021	Yes	No
Plain English results			31/03/2022	No	Yes