ISRCTN43138042 https://doi.org/10.1186/ISRCTN43138042

TARGeted Intraoperative radioTherapy as a tumour bed Boost (TARGIT-B): To compare targeted intra-operative radiotherapy boost with conventional external beam radiotherapy boost after lumpectomy for breast cancer in women with a high risk of local recurrence

Submission date 08/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/10/2012	**Overall study status** Completed	
Last Edited 01/11/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-a-boost-of-radiotherapy-given-during-surgery-and-standard-radiotherapy-after-surgery-for-early-breast-cancer-targit-b

Contact information

Type(s)
Principal investigator

Contact name
Dr Jayant Vaidya

Contact details
Clinical Trials Group, UCL Medical School
Centre for Clinical Science and Technology
Clerkenwell Building, Archway Campus
Highgate Hill
London
United Kingdom
N19 5LW
-
jayant.vaidya@ucl.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01792726

Protocol serial number
HTA 0/104/07, TARGIT Boost

Study information

Scientific Title
TARGIT-B: An international randomised controlled trial to compare targeted intra-operative radiotherapy boost with conventional external beam radiotherapy boost after lumpectomy for breast cancer in women with a high risk of local recurrence

Acronym
TARGIT-B

Study objectives
A pragmatic multi-centre randomised clinical trial to test whether TARGeted Intraoperative radioTherapy as a tumour bed Boost (TARGIT-B) is superior in terms of local relapse within the treated breast compared with standard postoperative external beam radiotherapy boost in women undergoing breast-conserving therapy who have a higher risk of local recurrence.

More details can be found at http://www.hta.ac.uk/project/2946.asp

Study protocol can be found at: http://www.hta.ac.uk/protocols/201001040007.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/01/2013, REC - Hampshire B (Formally NRES Committee South Central Portsmouth, Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8045; nrescommittee.southcentral-hampshireb@nhs.net), REC ref: 12/SC/0731(transferred from 13/LO/0083)

Study design
Pragmatic multi-centre randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early breast cancer

Interventions

Current interventions as of 09/05/2024:
Eligible patients are those with a higher risk (8% at 5 years) of local recurrence after breast-conserving surgery. After giving consent patients are randomised to either TARGIT Boost or external beam radiotherapy (EBRT) Boost. All patients will receive whole breast EBRT. They may receive any other adjuvant treatments as deemed necessary. The protocol recommends that patients be followed at 6 monthly intervals for five years and then annually for at least 10 years.

Experimental arm (TARGIT boost):
A tumour bed boost in the form of a single fraction of radiotherapy given intra-operatively and targeted to the tissues at the highest risk of local recurrence.

Control arm (external beam boost):
Standard post-operative external beam radiotherapy boost.

Previous interventions:
Eligible patients are those with a higher risk (8% at 5 years) of local recurrence after breast-conserving surgery. After giving consent patients are randomised to either TARGIT Boost or external beam radiotherapy (EBRT) Boost. All patients will receive whole breast EBRT. They may receive any other adjuvant treatments as deemed necessary. The protocol recommends that patients be followed at 6 monthly intervals for five years and then annually.

Experimental arm (TARGIT boost):
A tumour bed boost in the form of a single fraction of radiotherapy given intra-operatively and targeted to the tissues at the highest risk of local recurrence.

Control arm (external beam boost):
Standard post-operative external beam radiotherapy boost.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Local recurrence

Key secondary outcome(s))
1. Site of relapse within the breast
2. Relapse-free survival and overall survival
3. Local toxicity/morbidity

Completion date
31/10/2024

Eligibility

Key inclusion criteria
Patients diagnosed with breast cancer and suitable for conserving surgery and radiotherapy, with a cytological or histological confirmation of carcinoma can be included in the study once written informed consent is obtained. All patients should be available for regular follow-up

(according to local policies) for at least ten years.
At least one of these criteria must be satisfied:
1. Less than 46 years of age
2. More than 45 years of age, but with one of the following poor prognostic factors:
2.1. Lymphovascular invasion
2.2. Gross nodal involvement (not micrometastasis)
2.3. More than one tumour in the breast but still suitable for breast-conserving surgery through a single specimen
3. More than 45 years of age, but with at least two of the following poor prognostic factors
3.1. ER-negative
3.2. Grade 3 histology
3.3. Positive margins at first excision
4. Those patients with large tumours which have responded to neo-adjuvant chemo- or hormone therapy in an attempt to shrink the tumour and are suitable for breast-conserving surgery as a result
5. Lobular carcinoma or Extensive Intraductal Component (EIC)
6. A combination of high-risk factors are present (as predefined in the policy document) that give a high risk of local recurrence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
1684

Key exclusion criteria
1. Bilateral breast cancer at the time of diagnosis
2. Patients with any severe concomitant disease that may limit their life expectancy
3. Previous history of malignant disease does not preclude entry if the expectation of relapse-free survival at 10 years is 90% or greater (e.g., non-melanoma skin cancer, CIN etc)
4. No more than 30 days can have elapsed between last breast cancer surgery (not axillary) and randomisation for patients in the post-pathology stratification unless part of a specific clinical trial that addresses the question of timing or tumour bed can be reliably identified, e.g. by ultrasound

Date of first enrolment
01/03/2013

Date of final enrolment
14/06/2023

Locations

Countries of recruitment
United Kingdom

England

Australia

Canada

Denmark

France

Germany

Italy

Norway

Poland

Switzerland

United States of America

Study participating centre
Clinical Trials Group, UCL Medical School
London
United Kingdom
N19 5LW

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research Health Technology Assessment Programme - HTA (UK) ref: 10/104/07

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V7.0	15/11/2019	11/09/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes