

Extended follow up of the TARGIT-A trial

Submission date 26/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/09/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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>

Contact information

Type(s)

Scientific

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Contact details

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Additional identifiers

Protocol serial number

37219; HTA 14/49/13

Study information

Scientific Title

Extended follow up of the TARGIT-A trial

Study objectives

All UK patients who participated in the TARGIT-A Trial (<https://www.isrctn.com/ISRCTN34086741>) were initially treated for early breast cancer between 2000-2012. A total of 3451 patients from 33 hospitals in 11 countries participated in the trial and a comparison was made between traditional radiotherapy given over several weeks (external beam radiotherapy, EBRT) with TARGeted Intraoperative radioTherapy (TARGIT-IORT) as a single dose given during the operation to remove the breast cancer.

The trial was funded by the Health Technology Assessment (HTA) programme of the Department of Health, UK and sponsored by University College London. The results from this trial have been published in major medical journals and have already started changing the way breast cancer is treated around the world; please see www.targit.org.uk for more details.

The trialists would like to continue to collect data about the health status of all patients to find out about longer term differences in the effects of these treatments on health. An analysis of this information could improve treatment for patients with breast cancer. For this, HTA have granted further funding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Fulham Research Ethics Committee, 14/03/2018, REC ref: 18/LO/0181

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

All UK patients who participated in the TARGIT-A Trial were initially treated for early breast cancer between 2000-2012. A total of 3451 patients from 33 hospitals in 11 countries participated in the trial and a comparison was made between traditional radiotherapy given over several weeks (external beam radiotherapy, EBRT) with TARGeted Intraoperative radioTherapy (TARGIT-IORT) as a single dose given during the operation to remove the breast cancer. Data is collected about the health status of all patients to find out about longer term differences in the effects of these treatments on health. Patients are followed up through direct patient contact for 60 months and through national registries for up to 20 years.

Intervention Type

Other

Primary outcome(s)

Self-reported health status through direct patient contact [Time Frame: 60 months]

Key secondary outcome(s)

Death and new primary cancer data from UK patients, collected through the Office for National Statistics [Time Frame: Up to 20 years]

Completion date

31/01/2023

Eligibility

Key inclusion criteria

1. All patients who participated in the TARGIT-A trial
2. Female
3. 45 years and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Any patient who has withdrawn consent for further follow-up, or died
2. Any patient who is unable to give formal written consent

Date of first enrolment

30/04/2018

Date of final enrolment

31/01/2023

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

The Whittington Hospital NHS Trust

St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre

Royal Free London NHS Foundation Trust

Pond Street
London
United Kingdom
NW3 2QG

Study participating centre

Ninewells Hospital and Medical School

Dundee
United Kingdom
DD1 9SY

Study participating centre

Royal Hampshire County Hospital

Romsey Road
Winchester
United Kingdom
SO22 5DG

Study participating centre

University College London Hospitals NHS Foundation Trust

235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor information

Organisation

University College London

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

Individual participant data (IPD) sharing plan

All data obtained will be held securely in UCL. Patient identifiers (such as name, address, etc.) will be held on a separate Data Safe Haven which has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. This has been built using a walled garden approach, where the data is stored, processed and managed within the security of the system, avoiding the complexity of assured end point encryption. A file transfer mechanism enables information to be transferred into the walled garden simply and securely. Long term arrangements will be as per the sponsors SOP. On publication of the final analysis and closure of all sites, the main REC (HRA) will be notified using the appropriate forms. All essential documentation, CRFs and electronic records will be catalogued and boxed up. All duplicates and non-essential documentation will be confidentially destroyed. These boxes will be held off site within UCL's commercial storage, provided by Iron Mountain. These data will be held for 20 years, at the end of which they will also be confidentially destroyed.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version v1.0	10/11/2017	26/08/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes