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Extended follow up of the TARGIT-A trial

Submission date 26/03/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 25/04/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2021	**Condition category** Cancer	[_] Individual participant data [_] 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

Study website
https://www.journalslibrary.nihr.ac.uk/programmes/hta/144913/#/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 in 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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

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

Overall study start date
30/04/2018

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

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 3451; UK Sample Size: 714

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
England

Scotland

United Kingdom

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

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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, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A draft protocol for publication is in process. Planning to submit and publish protocol to open access journal of which details will be supplied once accepted. Planned publication of the study results in a high-impact peer reviewed journal

Intention to publish date
31/01/2024

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
Stored in repository

Study outputs

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