ISRCTN47437448 https://doi.org/10.1186/ISRCTN47437448

Randomised trial testing dose escalated intensity modulated radiotherapy in women with higher than average local tumour recurrence risk after breast conservation therapy for early breast cancer

Submission date
16/02/2007

Recruitment status
No longer recruiting

Registration date
17/04/2007

Overall study status
Ongoing

Last Edited
28/07/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-comparing-different-ways-of-giving-radiotherapy-for-early-stage-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00818051

Secondary identifying numbers
CCR2691

Study information

Scientific Title
Randomised trial testing dose escalated intensity modulated radiotherapy in women with higher than average local tumour recurrence risk after breast conservation therapy for early breast cancer

Acronym
IMPORT HIGH (Intensity Modulated and Partial Organ Radiotherapy - HIGH)

Study objectives
To test dose escalated intensity modulated radiotherapy after conservation therapy surgery for early breast cancer in women with higher than average local recurrence risk.

Related studies are registered with the following ISRCTNs:
ISRCTN12852634 - IMPORT LOW trial
ISRCTN18654225 - Evaluation of tumour bed localisation and image-guided radiotherapy techniques for breast radiotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 4 Research Ethics Committee, 30/05/2008, ref: 08/H0305/13

Study design
Prospective randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
The control arm will have standard dose radiotherapy to the whole breast Monday to Friday for 3 weeks (15 treatments). This will be followed by a sequential boost dose to the tumour bed Monday to Friday for a further eight treatments. The total number of treatments is 23.

Test arm 1 will have a lower dose of radiotherapy to the area of the breast furthest away from where the tumour used to be, the standard dose of radiotherapy to the area of the breast around where the tumour used to be and a boost dose to the tumour bed. These three treatments will be given simultaneously Monday to Friday for three weeks. The total number of treatments is 15.

Test arm 2 will have the same treatment as test arm 1 but the boost dose to the tumour bed will be higher. Again the total number of treatments is 15.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Current primary outcome measure as of 26/02/2019:
Local tumour control measured by reported ipsilateral events at 5 years

Previous primary outcome measure:
Palpable induration in the ipsilateral breast, measured at yearly follow-up visits by physician examination and also at baseline (before radiotherapy) and at years 3 and 5 by photographic assessment years. Outcome from these will be correlated at years 3 and 5.

Secondary outcome measures
Current secondary outcome measures as of 26/02/2019:
1. Induration in the ipsilateral breast by clinician assessed changes, patient reported changes, photographic assessments at baseline and 5 years
2. Other late adverse effects in normal tissues reported on CRFs by clinical assessment at 5 years
3. Quality of life reported by patients at baseline, 6 months, 1, 3 and 5 years
4. Location of tumour relapse in breast reported on CRFs and/or assessed by review of scans at 5 years
5. Contralateral primary tumours reported by CRFs at 5 years
6. Regional and distant metastases reported by CRFs at 5 years
7. Survival reported by CRFs at 5 years

Previous secondary outcome measures:
1. Quality of life, measured at baseline, 6 months and years 1, 3 and 5
Other secondary outcomes will be measured at annual follow up visits for 10 years and also during the trial by completion of case report forms:
2. Other late adverse effects of radiotherapy in normal tissues
3. Local tumour control
4. Location of tumour relapse in breast

5. Contralateral primary tumours
6. Regional and distant metastases
7. Survival

Overall study start date
23/01/2009

Completion date
16/09/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/02/2019:
1. Operable unilateral breast cancer (T1-3, pN0- pN3a, M0 at presentation)
2. Breast conserving surgery
3. Age greater than or equal to 18 years
4. Histological confirmation of invasive carcinoma
5. Complete microscopic resection
6. Patient requires a tumour bed boost plus whole breast radiotherapy for inclusion within the trial
7. Written informed consent and available for follow-up

Previous inclusion criteria:
1. Age greater than or equal to 18 years
2. Operable, unilateral breast cancer (T1-3, N0-1, M0 at presentation)
3. Breast conserving surgery
4. Histological confirmation of invasive carcinoma
5. Complete microscopic resection
6. Patient requires a tumour bed boost plus whole breast radiotherapy
7. Written informed consent and availability for follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2568

Total final enrolment
2621

Key exclusion criteria
Current exclusion criteria as of 26/02/2019:
1. Past history of malignancy except:
1.1. Basal cell skin cancer and CIN cervix uteri or
1.2. Non breast malignancy allowed if treated with curative intent and at least 5 years disease-free
2. Mastectomy
3. Concomitant chemotherapy (primary or sequential chemotherapy allowed).
4. Presence of ipsilateral breast implant

Previous exclusion criteria:
1. Previous malignancy (other than non-melanomatous skin cancer and Carcinoma In Situ [CIS] of the cervix)
2. Mastectomy
3. Concomitant chemotherapy (sequential chemotherapy allowed)
4. Radiotherapy prescription includes posterior axillary boost field

Date of first enrolment
04/03/2009

Date of final enrolment
16/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cancer Research
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

Website
http://www.icr.ac.uk/

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (ref: C1491/A16831)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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
The datasets generated during and/or analysed during the current study are/will be available upon request from the IMPORT Trial Team (import-icrctsu@icr.ac.uk). De-identified individual participant data, together with a data dictionary defining each field in the set, will be made available to other researchers on request from the time of publication. There is no time limit on applying for this data. Trial documentation including the protocol are available online. The ICR-CTSU supports wider dissemination of information from the research it conducts and increased cooperation between investigators. Trial data are obtained, managed, stored, shared, and

archived according to ICR-CTSU standard operating procedures to ensure the enduring quality, integrity, and utility of the data. Formal requests for data sharing are considered in line with ICR-CTSU procedures, with due regard given to funder and sponsor guidelines. Requests are via a standard proforma describing the nature of the proposed research and the extent of data requirements. Data recipients are required to enter a formal data-sharing agreement, which describes the conditions for release and requirements for data transfer, storage, archiving, publication, and intellectual property. Requests are reviewed by the trial management group in terms of scientific merit and ethical considerations, including patients' consent. Data sharing is undertaken if proposed projects have a sound scientific or patients' benefit rationale, as agreed by the trial management group and approved by the independent data monitoring and steering committee, as required. Restrictions relating to patients' confidentiality and consent will be limited by aggregating and anonymising identifiable patients' data. Additionally, all indirect identifiers that could lead to deductive disclosures will be removed in line with ICR-CTSU data-sharing guidelines.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/10/2006		Yes	No
Other publications	Forward planning analysis	01/04/2007		Yes	No
Other publications	Trial planning	15/03/2011		Yes	No
Interim results article	Results of observational sub-study comparing image-guided radiotherapy and standard imaging.	01/11/2014		Yes	No
Interim results article	Clinical impact results	01/03/2015		Yes	No
Abstract results	3-year adverse event results presented at San Antonio Breast Cancer Symposium	15/02/2019	30/12/2022	No	No
Abstract results	Presented at ESTRO	29/08/2021	30/12/2022	No	No
Results article		08/06/2023	12/06/2023	Yes	No
Results article	5-year trends and baseline predictors of patient-reported adverse events	23/07/2025	28/07/2025	Yes	No