

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

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|--------------------------|-----------------------------|--|
| Submission date | Recruitment status | <input checked="" type="checkbox"/> Prospectively registered |
| 16/02/2007 | No longer recruiting | <input checked="" type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 17/04/2007 | Deferred | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 27/11/2025 | Cancer | |

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

Contact name

Prof Charlotte Coles

Contact details

University of Cambridge
Oncology Centre, Box 193
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT00818051

Protocol serial number

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

Study type(s)

Treatment

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 3 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.

Added 27/11/2025:

Additional Data Linkage Information:

Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website:
<https://www.icr.ac.uk/interact>.

Intervention Type

Other

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

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

United Kingdom

England

Study participating centre

Institute of Cancer Research

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Sutton

England

SM2 5PT

Sponsor information

Organisation

Institute of Cancer Research (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

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-icrcts@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

[Results article](#)

| Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------|------------|----------------|-----------------|
| 08/06/2023 | 12/06/2023 | Yes | No |

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