ISRCTN12852634 https://doi.org/10.1186/ISRCTN12852634

Randomised trial testing Intensity Modulated radiotherapy and Partial Organ RadioTherapy following breast conservation surgery for early breast cancer

Submission date
11/07/2006

Recruitment status
No longer recruiting

Registration date
28/07/2006

Overall study status
Completed

Last Edited
27/11/2025

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-different-ways-of-giving-radiotherapy-for-low-risk-early-stage-breast-cancer

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Coles

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

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00814567

Protocol serial number
CCR2690

Study information

Scientific Title
Randomised trial testing Intensity Modulated radiotherapy and Partial Organ RadioTherapy following breast conservation surgery for early breast cancer

Acronym
IMPORT LOW

Study objectives
To test partial breast radiotherapy delivered using intensity modulated techniques following complete local tumour excision of low risk early stage breast cancer.

A related study IMPORT HIGH is registered with ISRCTN47437448.

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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee B, 12/10/2006, ref: 06/Q1605/128

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This is a randomised controlled trial for patients at low risk of local recurrence (less than 1% annual risk local recurrence after radiotherapy).

Control group: current standard radiotherapy to the whole breast
Test arm one: reduced radiotherapy to the whole breast with standard radiotherapy to the partial breast
Test arm two: standard radiotherapy to the partial breast only

Intervention Type
Other

Primary outcome(s)
Local tumour control in the ipsilateral breast

Key secondary outcome(s))
1. Location of tumour relapse
2. Contralateral primary tumours
3. Regional and distant metastases
4. Late adverse effects in normal tissues
5. Quality of life (QL)
6. Economic evaluation

Completion date
01/10/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/02/2019:
1. Age greater than or equal to 50 years
2. Primary breast conservation surgery +/- adjuvant systemic therapy
3. Pathological tumour size 3.0 cm pT1-2 (< 3.1 cm, maximum microscopic diameter of invasive component)
4. Invasive adenocarcinoma (excluding invasive carcinoma of classical lobular type)
5. Unifocal disease
6. Grade I, II or III
7. Lymphovascular invasion present or absent
8. Axillary lymph nodes negative or 1 to 3 nodes positive (pN0 or pN+(1-3))
9. Minimum microscopic margin of non-cancerous tissue 2 mm (excluding deep margin if this is at deep fascia)
10. No blood-borne metastases

Previous inclusion criteria:
1. Age greater than or equal to 50 years
2. Primary breast conservation surgery +/- adjuvant systemic therapy
3. Pathological tumour size less than or equal to 2.0 cm pT1a-c (maximum microscopic diameter of invasive component)
4. Invasive adenocarcinoma (excluding invasive carcinoma of classical lobular type)
5. Unifocal disease (Grade I or II)
6. Minimum microscopic margin of non-cancerous tissue greater than or equal to 2 mm (excluding deep margin if this is at deep fascia)
7. No lympho-vascular invasion
8. Axillary lymph nodes negative, PN0 (sentinel node biopsy & isolated tumour cells less than 0.2 mm allowed)
9. No blood borne metastases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
100 years

Sex
Female

Total final enrolment
2018

Key exclusion criteria
Current exclusion criteria as of 26/02/2019:
1. Previous malignancy (other than non-melanomatous skin cancer)
2. Mastectomy
3. Invasive carcinoma of classical lobular type
4. Primary endocrine therapy or chemotherapy (neo-adjuvant endocrine therapy is permissible as long as the tumour is <3.0 cm and all other inclusion criteria are met. Primary endocrine therapy as a replacement for surgery is not permissible)
5. Concurrent chemo-radiotherapy

Previous exclusion criteria:
1. Previous malignancy (other than non-melanomatous skin cancer)
2. Mastectomy
3. Invasive carcinoma of classical lobular type
4. Primary endocrine therapy or chemotherapy (neo-adjuvant endocrine therapy is permissible as long as the tumour is less than 2.0 cm and all other inclusion criteria are met. Primary endocrine therapy as a replacement for surgery is not permissible)
5. Concurrent chemo-radiotherapy

Date of first enrolment
01/03/2007

Date of final enrolment
05/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Institute of Cancer Research
-
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)

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

Funder Name
Department of Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/09/2017		Yes	No
Results article	Patient-reported outcome measures substudy at 5 years	01/02/2019	20/12/2019	Yes	No
Results article	10-year outcomes were analysed in the intention-to-treat population	11/06/2025	16/06/2025	Yes	No