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
20/12/2019

Condition category
Cancer

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

Plain English Summary
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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00814567

Secondary identifying numbers
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 hypothesis
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.

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 randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Condition
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 measure
Local tumour control in the ipsilateral breast

Secondary outcome measures
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

Overall study start date
01/03/2007

Overall study end date
01/10/2020

Eligibility

Participant 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

Age group
Adult

Sex
Female

Target number of participants
1,935

Total final enrolment
2018

Participant 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

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1. Previous malignancy (other than non-melanomatous skin cancer)
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5. Concurrent chemo-radiotherapy

Recruitment start date
01/03/2007

Recruitment end date
05/10/2010

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
Charity

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/09/2017		Yes	No
Results article	results	01/02/2019	20/12/2019	Yes	No