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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
11/07/2006		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
28/07/2006	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
16/06/2025	Cancer				

#### 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

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

#### 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 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.

#### 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

#### 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 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

#### 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

#### Age group

Adult

#### Sex

**Female** 

### Target number of participants

1,935

#### 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)
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- 3. Invasive carcinoma of classical lobular type
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- 5. Concurrent chemo-radiotherapy

#### Date of first enrolment

01/03/2007

#### Date of final enrolment

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	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