

# Standardisation of breast radiotherapy (START) trial

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
[http://www.icr.ac.uk/research/research\\_sections/clinical\\_trials/clinical\\_trials\\_list/2414\\_disease.shtml](http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2414_disease.shtml)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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**Contact details**  
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United Kingdom  
SM2 5PT

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00005588

## Secondary identifying numbers

G9600656

# Study information

## Scientific Title

Standardisation of breast radiotherapy (START) trial

## Acronym

START

## Study objectives

To test the effects of radiotherapy schedules using fraction sizes larger than 2.0 Gy in terms of normal tissue responses, loco-regional tumour control, quality of life and economic consequences in women prescribed postoperative radiotherapy for early breast cancer.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 30 July 2008: South East London (MREC 98/96) - approved 30/09/1998

## Study design

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 below to request a patient information sheet

## Health condition(s) or problem(s) studied

Breast cancer

## Interventions

Radiotherapy schedules using fraction sizes larger than 2.0 Gy

## Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

In this study several endpoints are being investigated (tumour recurrence, normal tissue effect, quality of life). It is intended that each will be analysed separately. If there is discordance between the endpoints in terms of treatment outcome this will allow discussion of clinical trade-offs. In a subset of patients there will be a detailed assessment of quality of life. Health economic consequences will also be determined.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1999

**Completion date**

24/10/2002

## Eligibility

**Key inclusion criteria**

1. Patients must be 18 years and above, have operable unilateral breast cancer (T1-3, NO-1, MO at presentation)
2. There must be histological confirmation of invasive carcinoma and complete macroscopic excision of tumour by breast conserving surgery or mastectomy
3. The patient must consent to be part of the study and be available for follow-up

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

4451 patients recruited up to 24/10/2002. 5 years follow up

**Total final enrolment**

4451

**Key exclusion criteria**

Patients requiring axillary radiotherapy after greater than a level 1 axillary dissection or after greater than 10 lymph nodes have been removed

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

24/10/2002

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Radiotherapy**

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**

Department of Health

**Funder Name**

Medical Research Council (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Cancer Research 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

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	March results on 'Trial A'	29/03/2008		Yes	No
<a href="#">Results article</a>	April results on 'Trial B'	01/04/2008		Yes	No
<a href="#">Results article</a>	results	01/03/2010		Yes	No
<a href="#">Plain English results</a>	START A		28/10/2021	No	Yes
<a href="#">Plain English results</a>	START B		25/10/2022	No	Yes