# Standardisation of breast radiotherapy (START) trial

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/04/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/04/2000	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
25/10/2022	Cancer			

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof John Yarnold

#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00005588

Protocol serial number

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

#### Study type(s)

Treatment

## 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(s)

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 tradeoffs. In a subset of patients there will be a detailed assessment of quality of life. Health economic consequences will also be determined.

#### Key secondary outcome(s))

Not provided at time of registration

# 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

# 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

United Kingdom

England

#### Study participating centre

## **Department of Radiotherapy**

Sutton United Kingdom SM2 5PT

# Sponsor information

# Organisation

Institute of Cancer Research (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, 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

Not provided at time of registration

# IPD sharing plan summary

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	March results on 'Trial A'	29/03/2008		Yes	No
Results article	April results on 'Trial B'	01/04/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results	START A		28/10/2021	No	Yes
Plain English results	START B		25/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes