

Standardisation of breast radiotherapy (START) trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Yarnold

Contact details
Department of Radiotherapy
Royal Marsden Hospital
The Institute of Cancer Research
Downs Road
Sutton
United Kingdom
SM2 5PT

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 trade-offs. 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, Medical Research Committee and Advisory 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
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