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Standardisation of breast radiotherapy (START) trial

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

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

Contact information

Type(s)
Scientific

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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?
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