ISRCTN62488883 https://doi.org/10.1186/ISRCTN62488883

Prospective randomised clinical trial testing 5.7 Gy and 6.0 Gy fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control

Submission date
01/10/2004

Recruitment status
No longer recruiting

Registration date
10/01/2005

Overall study status
Completed

Last Edited
06/10/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-different-ways-of-giving-radiotherapy-for-women-with-early-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00107497

Study information

Scientific Title
Prospective randomised clinical trial testing 5.7 Gy and 6.0 Gy fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control

Acronym
FAST

Study objectives
Aim: to test 5 fractions of 5.7 Gy and 6.0 Gy against 25 fractions of 2.0 Gy in terms of late normal tissue effects and tumour control in women prescribed whole breast radiotherapy (no boost) after local excision of early breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 30/07/2008: South West MREC (04/MRE06/17) - approved 30/06/2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early breast cancer

Interventions
Control arm: 50 Gy in 25 fractions over 5 weeks
Test arm 1: 30 Gy in 5 fractions over 5 weeks
Test arm 2: 28.5 Gy in 5 fractions over 5 weeks

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Change in photographic breast appearance.

Key secondary outcome(s))
Tumour recurrence in the breast.

Completion date

09/03/2007

Eligibility

Key inclusion criteria
1. Women over the age of 49 years with invasive breast cancer who have had breast preserving surgery
2. Tumour size less than 3 cm with complete resection and node negative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
915

Key exclusion criteria
1. Age less than 50 years
2. Mastectomy
3. Lymphatic radiotherapy or radiotherapy boost
4. Neoadjuvant or adjuvant cytotoxic therapy

Date of first enrolment
01/10/2004

Date of final enrolment
09/03/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic 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
Research costs are covered by the Cancer Research UK (CRUK) core grant held by the Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No
Results article		14/07/2020	06/10/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes