

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/10/2021	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00107497

Protocol serial number

N/A

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes