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# 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.

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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 |