

# 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

<b>Submission date</b> 01/10/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2021	<b>Condition category</b> 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>

## Study website

[http://www.icr.ac.uk/research/research\\_sections/clinical\\_trials/clinical\\_trials\\_list/6120\\_disease.shtml](http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/6120_disease.shtml)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

NCT00107497

**Secondary identifying numbers**

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

### **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**

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 measure**

Change in photographic breast appearance.

### **Secondary outcome measures**

Tumour recurrence in the breast.

### **Overall study start date**

01/10/2004

### **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

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

900 (recruited as of 09/03/2007)

### **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**

England

United Kingdom

**Study participating centre**

Academic 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/index.shtml>

**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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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?
<a href="#">Results article</a>	results	01/07/2011		Yes	No
<a href="#">Results article</a>		14/07/2020	06/10/2021	Yes	No