

# A clinical trial testing a 1-week schedule of whole breast radiotherapy against a 3-week schedule

<b>Submission date</b> 18/05/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2011	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/11/2025	<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-giving-1-week-radiotherapy-breast-cancer-fast-forward>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

58575

### Protocol serial number

## Study information

### Scientific Title

Randomised clinical trial testing a 1-week course of curative whole breast radiotherapy against a standard 3-week schedule in terms of local cancer control and late adverse effects in patients with early breast cancer

### Acronym

FAST-Forward

### Study objectives

To identify a 5-fraction schedule of curative radiotherapy delivered in one week that is at least as effective and safe as the UK standard 15-fraction regimen after primary surgery for early breast cancer.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 02/09/2011, NRES Committee South East Coast - Kent (now London - Brighton and Sussex REC, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8241; brightonandsussex.rec@hra.nhs.uk), REC ref: 11-LO-0958

### Study design

Phase III randomized controlled multi-centre trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Breast cancer

### Interventions

Patients will be randomised equally between a standard 3-week schedule and two 1 week test schedules of whole breast radiotherapy

Whole breast radiotherapy schedules:

Standard group - 40 Gy in 15 fractions over 15 days (not weekends)

Test group 1 - 27 Gy in 5 fractions over 5 days (not weekends)

Test group 2 - 26 Gy in 5 fractions over 5 days (not weekends)

Patients will be followed up for a minimum of 10 years.

There are Quality of Life and a photographic sub-studies, each with 2196 patients. Quality of Life questionnaires will be completed at baseline, 6, months and 2, 5 and 10 years post randomisation. Photographs will be taken at baseline and 2, 5 and 10 years post randomisation.

Added 27/11/2025:

Additional Data Linkage Information:

Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website:

<https://www.icr.ac.uk/interact>.

## **Intervention Type**

Other

## **Primary outcome(s)**

Ipsilateral local tumour control: Will be reported at the annual follow up visits. The tests will be performed when the need arises i.e. when the patient feels unwell or reports another lump etc. The tests will be carried out as routine clinical examinations i.e. X rays, computerised tomography (CT) scans, magnetic resonance imaging (MRI), ultrasound.

## **Key secondary outcome(s)**

1. Early and late adverse effects in normal tissues
2. Quality of life at baseline, 6, months and 2, 5 and 10 years post randomisation
3. Contralateral primary tumours, regional and distant metastases
4. Survival

## **Completion date**

02/10/2028

# **Eligibility**

## **Key inclusion criteria**

1. Age more than or equal to 18 years
2. Female or male
3. Invasive carcinoma of the breast
4. Breast conservation surgery or mastectomy (reconstruction allowed but not with implant. Tissue expanders with distant metal ports are allowed)
5. Axillary staging and/or dissection
6. Complete microscopic excision of primary tumour
7. Stage pT1-3 pN0-1 M0 disease
8. Written informed consent
9. Able to comply with follow up

Concurrent trastuzumab and hormone therapy is allowed

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

4579

**Key exclusion criteria**

1. Past history of malignancy except basal cell skin cancer and cervical intraepithelial neoplasia (CIN) or non-breast malignancy allowed if treated with curative intent and at least 5 years disease free
2. Contralateral breast cancer, including ductal carcinoma in-situ (DCIS), irrespective of date of diagnosis
3. Breast reconstruction using implants
4. Concurrent cytotoxic chemotherapy (sequential neoadjuvant or adjuvant cytotoxic therapy allowed)
5. Radiotherapy to any regional lymph node areas (excepting lower axilla included in standard tangential fields to breast/chest wall)

**Date of first enrolment**

01/09/2011

**Date of final enrolment**

02/10/2018

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Academic Radiotherapy**

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Sutton

England

SM2 5PT

**Sponsor information**

## Organisation

Institute of Cancer Research

## ROR

<https://ror.org/00dpztj76>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### 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	23/05/2020	26/06/2020	Yes	No
<a href="#">Results article</a>		01/11/2023	23/11/2023	Yes	No
<a href="#">Results article</a>		04/05/2025	19/05/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			03/05/2022	No	Yes