

# Can we safely reduce the number of days of radiotherapy needed to treat people with breast cancer who need boost treatment?

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| <b>Registration date</b><br>03/03/2025 | <b>Overall study status</b><br>Ongoing  | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>03/03/2025       | <b>Condition category</b><br>Cancer     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Each year, 37,000 people in the UK with breast cancer receive radiotherapy, which uses radiation to kill cancer cells. Most people can now be treated over 5 days, but about 10,000 still need up to 23 days of treatment because they require an extra dose called a boost. This study aims to find out if the boost can be given within a 5-day radiotherapy course, comparing two different boost doses over 5 days with the standard 15-day boost dose.

### Who can participate?

People with breast cancer who need a boost dose as part of their radiotherapy treatment can participate. Participants will be invited from 50 UK radiotherapy centres.

### What does the study involve?

Participants will be randomly placed into one of three groups by a computer:

One group will receive the boost dose over 15 days.

Two groups will receive the boost dose over 5 days, with different boost doses for each group. Participants will provide information about side effects, changes to the treated breast, extreme tiredness, and quality of life for five years.

What are the possible benefits and risks of participating? The study aims to show that the 5-day treatment is as effective as the 15-day treatment in preventing cancer from returning, with the same or fewer side effects and faster recovery. Risks include potential side effects from radiotherapy and the possibility that the shorter treatment may not be as effective.

### Where is the study run from?

Institute of Cancer Research - Clinical Trials and Statistics Unit (UK).

### When is the study starting and how long is it expected to run for?

April 2025 to September 2033

Who is funding the study?

The study is funded by the National Institute for Health and Care Research - Health Technology Assessment (NIHR-HTA) programme (UK).

Who is the main contact?

Institute of Cancer Research - Clinical Trials and Statistics Unit

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## Contact information

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**Additional identifiers****Integrated Research Application System (IRAS)**

341881

**Central Portfolio Management System (CPMS)**

57885

**National Institute for Health and Care Research (NIHR)**

157800

**Protocol serial number**

ICR\_CTSU/2024/10088

**Study information****Scientific Title**

A randomised clinical trial testing a 1-week schedule of curative simultaneous integrated boost radiotherapy against a standard 3-week schedule in patients with early breast cancer

**Acronym**

FAST-Forward Boost

**Study objectives**

Local recurrence rates at 5-years will be no higher with appropriately dosed 1-week Simultaneous Integrated Boost radiotherapy (SIB RT) than with 3-week SIB radiotherapy and that this can be achieved without an increase in normal tissue side-effects

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 14/01/2025, London - South East REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8222; londonse.rec@hra.nhs.uk), ref: 24/LO/0910

**Study design**

Phase III multi-centre randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Breast cancer

## Interventions

Patients will be treated using standard radiotherapy to the breast +/- nodes with a SIB to the tumour bed and randomised on a 1:1:1 basis to one of the following schedules:

- Standard radiotherapy to the breast +/- nodes using a schedule of 40Gy/15Fr over 3 weeks with a 48Gy/15Fr simultaneous integrated boost (SIB) of the tumour bed (Control Group)
- 26Gy/5Fr over 1 week with a 31Gy/5Fr SIB (Test Group 1)
- 26Gy/5Fr over 1 week with a 30Gy/5Fr SIB (Test Group 2)

## Radiotherapy treatment

All patients will attend the radiotherapy department for a planning CT scan so their radiotherapy treatment can be planned.

Once the treatment has been planned. The patient will start their radiotherapy treatment. Treatment is usually given daily on week days. Those in the control group will have their radiotherapy treatment in 15 treatments, the test groups will have their radiotherapy in 5 treatments.

## Questionnaires

For those taking part in the early side-effects sub-study, questionnaires about side-effects will need to be completed by the patient prior to radiotherapy, weekly for 7 weeks from start of radiotherapy and at 3 months.

All patients will be asked to complete questionnaire booklets pre treatment and at weeks 1, 3 and 5 from the start of radiotherapy then at 3 months, 1, 2, 3, 4 and 5 years.

## Follow up

For those taking part in the early side-effects sub-study:

Control group: will also be reviewed at weeks 1, 3, 5 and 7 from the start of radiotherapy

Test Groups: will also be reviewed at weeks 1, 3, 5 and 7 from the start of radiotherapy

All patients will be reviewed by the clinical team at 3 months, 1 years, 3 years and at 5 years.

## Intervention Type

Procedure/Surgery

## Primary outcome(s)

Ipsilateral breast tumour recurrence (IBTR) measured using patient records at 5 years

## Key secondary outcome(s)

1. Patient-reported acute radiotherapy adverse effects, with a focus on skin, breast, and oesophageal effects, are measured using PRO-CTCAE and trial-specific questionnaires at baseline, weekly for 7 weeks from the start of radiotherapy, and at 3 months

2. Patient-reported late effects on quality of life, with a focus on breast symptoms and shoulder

- /arm functioning, are measured using EORTC QLQ BR-23 and trial-specific questionnaires at baseline, weeks 1, 3, and 5 from the start of radiotherapy, and at 3 months, 1, 2, 3, 4, and 5 years
3. Patient-reported fatigue is measured using EORTC QLQ FA-12 at baseline, weeks 1, 3, and 5 from the start of radiotherapy, and at 3 months, 1, 2, 3, 4, and 5 years
  4. Health-related quality of life is measured using EORTC QLQ C-30 and EQ5D-5L at baseline, weeks 1, 3, and 5 from the start of radiotherapy, and at 3 months, 1, 2, 3, 4, and 5 years
  5. Body image is measured using the Body Image Scale (BIS) at baseline, weeks 1, 3, and 5 from the start of radiotherapy, and at 3 months, 1, 2, 3, 4, and 5 years
  6. Clinician-reported acute radiotherapy adverse effects, with a focus on skin, oesophageal, and lung toxicity, are measured using CTCAE v5.0 and RTOG at baseline, weekly for 7 weeks from the start of radiotherapy, and at 3 months
  7. Clinician-reported breast oedema is measured using trial-specific tools at baseline, weekly for 7 weeks from the start of radiotherapy, and at 3 months
  8. Clinician-reported late radiotherapy adverse effects, with a focus on normal tissue effects and cosmesis, are measured using tools developed in previous breast radiotherapy trials and the Harvard-Harris scale at baseline, 3 months, 1, 3, and 5 years
  9. Clinician-reported lung toxicity is measured using RTOG at baseline, 3 months, 1, 3, and 5 years
  10. Recurrence-free survival, breast cancer-related survival, and overall survival are measured using NHS routinely collected data at baseline, 3 months, 1, 3, and 5 years
  11. Cost-effectiveness is measured using health economic analysis incorporating data on patient-reported health resource use, out-of-pocket expenses, and health status (EQ5D-5L) at baseline, 3 months, 1, 3, and 5 years

### **Completion date**

30/09/2033

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq$ 18 years
2. Histologically confirmed breast cancer (T1-T3, N0-3, M0) (multifocal disease is allowed) requiring a tumour bed boost plus whole breast radiotherapy +/- radiotherapy to nodes\* (axilla +/- internal mammary chain) or DCIS (Tis, N0-3, M0) requiring a tumour bed boost according to local centre policy
3. Treated with breast conservation surgery
4. Complete microscopic resection (invasive cancer and/or DCIS clear of ink on radial margins or, if at margin, surgeon confirms no further breast tissue to excise)
5. Patient can provide informed consent

\* Axilla levels as per MDM recommendation

NB Patients with synchronous bilateral breast cancer can be included as long as the disease on at least one side fulfils the inclusion criteria above. Where the patient has synchronous bilateral disease and needs a tumour bed boost on both sides, both sides will need to fulfil the inclusion criteria for the patient to be eligible for the trial

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Treated with ipsilateral mastectomy
2. Previous radiotherapy to ipsilateral chest area that precludes delivery of a radical dose of adjuvant radiotherapy to the breast with tumour bed boost. NB for any scenarios where there is overlap with previous radiotherapy approval must be sought from the FAST-Forward Boost trial team prior to randomisation
3. Presence of metastatic disease
4. Unavailable for any trial related follow-up
5. History of malignancy except non-melanomatous skin cancer, CIS cervix, previously unirradiated precancerous changes in the breast (including ductal carcinoma in-situ and lobular carcinoma in-situ), and non-breast malignancy if curative intent and at least 5 years disease free
6. Pregnant and/or currently breast feeding
7. Participating in the PARABLE trial

**Date of first enrolment**

01/04/2025

**Date of final enrolment**

30/09/2028

**Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Ireland

**Study participating centre**

**Royal Marsden Hospital**

Royal Marsden Hospital

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**Study participating centre**  
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**The Christie**  
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**Belfast City Hospital**  
51 Lisburn Rd  
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**Study participating centre**  
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**Study participating centre**  
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OX3 7LE

**Study participating centre**  
**Clatterbridge Cancer Centre**  
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CH63 4JY

**Study participating centre**

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**Sponsor information****Organisation**

Institute of Cancer Research

**ROR**

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

**Funder(s)**

Funder type

Government

**Funder Name**

National Institute for Health and Care Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**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**

Data sharing statement to be made available at a later date