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

Submission date 19/02/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/03/2025	**Overall study status** Ongoing	
Last Edited 03/03/2025	**Condition category** Cancer	

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?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
341881

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57885, NIHR157800, 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; londonsoutheast.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 >=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

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Royal Marsden Hospital
Royal Marsden Hospital
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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