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A clinical trial testing a one week schedule of whole breast radiotherapy against a three week schedule

Submission date 18/05/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/05/2011	**Overall study status** Ongoing	
Last Edited 19/05/2025	**Condition category** Cancer	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
58575

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
HTA 09/01/47, ICR-CTSU/2010210026, IRAS 58575, NIHR150755

Study information

Scientific Title
Randomised clinical trial testing a one week course of curative whole breast radiotherapy against a standard three 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/clinical-trials/fast_forward_page

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.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4600

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
England

United Kingdom

Study participating centre

Academic Radiotherapy
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute of Cancer Research

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3PR

Sponsor type
Research organisation

ROR
https://ror.org/00dpztj76

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	23/05/2020	26/06/2020	Yes	No
Plain English results			03/05/2022	No	Yes
Results article		01/11/2023	23/11/2023	Yes	No
Results article		04/05/2025	19/05/2025	Yes	No