

Optimisation and individualisation of HeartSparing breast radiotherapy techniques (The HeartSpare Study): Stage II

Submission date 24/04/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-different-techniques-protect-heart-from-radiation-during-radiotherapy-breast-cancer-the-heartspare-study>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

14269

Study information

Scientific Title

Optimisation and individualisation of HeartSparing breast radiotherapy techniques (The HeartSpare Study): Stage II multicentre, non-randomised intervention trial

Acronym

The HeartSpare Study (Stage II)

Study objectives

A multicentre non-randomised intervention trial investigating whether the roll-out of voluntary deep-inspiratory breath-hold (v_DIBH) in the context of a HTA-funded multicentre trial of breast radiotherapy fractionation (the FAST-Forward trial <http://www.controlled-trials.com/ISRCTN19906132>) confirms effective heart-sparing in women undergoing breast radiotherapy following excision of early breast cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Fulham, 18/02/2013, ref: 13/LO/0181

Study design

Multicentre non-randomised interventional trial; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Radiotherapy using v_DIBH: Patients will receive their radiotherapy using the v_DIBH technique

Study Entry : Registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Percentage of patients in whom a reduction in mean LAD dose (Gy) is achieved with v_DIBH measured at end of study

Key secondary outcome(s)

1. Costs of techniques (equipment and time to scan/treat) measured at end of study
2. Difference in mean doses (Gy) to heart, ipsilateral lung and whole lungs, and maximum LAD dose measured at end of study

3. Interfraction reproducibility of patient position measured at end of study
4. Patient and radiographer satisfaction with positioning technique (questionnaire) measured at end of study.
5. Proportion of patients in whom prone position would have been optimal measured at end of study
6. Time spent in various activities / stages of treatment planning and delivery measured at end of study

Completion date

02/05/2014

Eligibility

Key inclusion criteria

1. Women or men with left-sided breast cancer
2. Recommendation for whole breast or chest wall RT within FAST-Forward trial
3. Patients with any heart tissue in a tangential RT field placed according to standard anatomical borders
3. Any breast volume
4. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
5. Patients able to tolerate breath-hold

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Right-sided breast cancer
2. Ineligible for whole breast or chest wall RT within FAST-Forward trial
3. Patients with micro- or macro-scopic disease on sentinel node biopsy who have not undergone completion axillary node clearance
4. Previous radiotherapy to any region above the diaphragm

Date of first enrolment

03/06/2013

Date of final enrolment

02/05/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Downs Road

Sutton

United Kingdom

SM2 5PT

Sponsor information

Organisation

Royal Marsden NHS Foundation Trust (UK)

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme ref: PB-PG-1010-23003

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes