

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

<b>Submission date</b> 24/04/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/04/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/01/2017	<b>Condition category</b> 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

03/06/2013

## **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  $\leq 1$
5. Patients able to tolerate breath-hold

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

UK Sample Size: 75; Description: 13 patients will be recruited from each of the five participating centres.

**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**

England

United Kingdom

**Study participating centre**

**Downs Road**

Sutton

United Kingdom

SM2 5PT

**Sponsor information****Organisation**

Royal Marsden NHS Foundation Trust (UK)

**Sponsor details**

Downs Road

Sutton

England

United Kingdom

SM2 5PT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalmarsden.nhs.uk/>

**ROR**

## 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

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No