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

Submission date 24/04/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/04/2013	**Overall study status** Completed	
Last Edited 06/01/2017	**Condition category** Cancer	

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

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 <=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

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

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?
HRA research summary			28/06/2023	No	No