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The HeartSpare Study

Submission date 06/02/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/02/2012	**Overall study status** Completed	
Last Edited 19/02/2020	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/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
11499

Study information

Scientific Title
Optimisation and individualisation of heart-sparing breast radiotherapy techniques: a randomised controlled trial

Study objectives
Single-centre randomised, non-blinded crossover trials investigating the impact of different heart-sparing breast radiotherapy techniques upon normal-tissue doses and upon reproducibility of patient position in women undergoing breast radiotherapy following excision of early breast cancer.

Hypotheses:
1. v_DIBH will be equivalent to ABC_DIBH in terms of dosimetric sparing of heart tissue, patient comfort, and set-up reproducibility, but at a reduced cost (due to the need for specialised equipment for ABC_DIBH)
2. Prone treatment is likely to be dosimetrically superior to optimal DIBH for the population of larger-breasted women
3. The optimal heart-sparing breast radiotherapy technique (DIBH versus prone positioning) will be individualisable to each patient based on their anatomical features

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11499

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London Riverside, 25/01/2012, ref: 12/LO/0015

Study design
Randomised non-blinded interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Study design:
These are single-centre non-blinded randomised cross-over trials (RCT) comparing i) treatment in voluntary deep inspiartor breath-hold (v_DIBH) versus Active Breathing Control deep inspiratory breath-hold (ABC_DIBH) in women of all breast volumes (Group A), and ii) treatment in DIBH versus prone position in women with larger breast volumes (>750cm3) (Group B). Within each cohort, patients will be randomised to start with one technique and to cross over to the other after 7 fractions.

Treatment planning: patient positioning and imaging:
All patients will receive training in holding their breath comfortably for up to 20 seconds. They will then undergo two radiotherapy planning CT scans. Patients in Group A will receive one scan in ABC_DIBH and a second scan in v_DIBH. Patients in Group B will undergo one scan in optimal DIBH (as determined by results from Group A) and one on their front (prone).

Treatment planning: study assessments:
1. 3D-CT planning scans in ABC_DIBH and v_DIBH (Group A)
2. 3D-CT planning scans in optimal DIBH and prone (Group B)
3. Scan times for each technique
4. Patient comfort and acceptability questionnaire following above scans

Treatment planning: target volume definition and radiotherapy planning:
Whole breast clinical target volume (WBCTV), contralateral breast tissue, lungs, heart, left anterior descending coronary artery (LAD) and ribcage will be outlined. For each technique, whole breast RT will be forward planned in 3D using multiple static opposed tangential fields, aiming to cover 90% of WBCTV with the 95% isodose, with hotspots ≥ 107cm3 limited to ≤ 2cm3. 40Gy in 15 fractions over 3 weeks will be prescribed to the 100% isodose (using 6-10MV photons).

During radiotherapy course: summary of study assessments
1. Daily EPI including cine-loop
2. Low dose CT verification imaging
3. Treatment times
4. Patient comfort and acceptability questionnaire
5. Radiographer satisfaction questionnaire

Follow-up assessments
No further investigations are required as part of the study following completion of radiotherapy. No long-term trial-related follow-up is required, although patients will be reviewed in the breast clinic as part of their standard follow-up.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Group A: Reproducibility - interfraction reproducibility of patient position (mean daily displacements of chest wall) in v_DI

Secondary outcome measures
Group B: Difference in mean LAD NTDmean - difference in mean normal tissue dose (NTDmean) (Gy) to left anterior-descending coronary artery

Overall study start date
01/02/2012

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Complete microscopic excision of early stage invasive ductal or lobular carcinoma (pT1-3b N0-1 M0) of the left breast following breast conservation surgery or mastectomy
2. Recommendation for whole breast (Group A and B) or chest wall radiotherapy (Group A only) (with or without tumour bed boost)
3. Age =18
4. Performance status =1
5. Patients able to tolerate breath-ho
6. Target Gender: Female
7. Lower Age Limit is 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 73; UK Sample Size: 73; Description: Group A: 23 patients; Group B: 50 patients

Key exclusion criteria
1. Requirement for nodal irradiaion
2. Patients with micro- or macro-scopic disease on sentinel node biopsy who have not undergone completion axillary node clearance
3. Previous radiotherapy to any region above the diaphragm

Date of first enrolment
01/02/2012

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Marsden NHS Foundation Trust
Surrey
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Sponsor information

Organisation
The Royal Marsden Foundation Trust (UK)

Sponsor details
Institute of Cancer Research
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Sponsor type
Hospital/treatment centre

Website
http://www.royalmarsden.nhs.uk/

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Government

Funder Name

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?
Plain English results				No	Yes
Results article	results	01/08/2013		Yes	No
Results article	results	01/01/2015		Yes	No