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A Randomised Controlled Trial: Investigation of Radiotherapy Dose Inhomogeneity and Cosmetic Outcome in Patients with Early Breast Cancer

Submission date 10/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/02/2006	**Overall study status** Completed	
Last Edited 22/08/2012	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-to-see-if-intensity-modulated-radiotherapy-improves-cosmetic-appearance-for-breast-cancer-patients

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Cambridge IMRT

Study objectives
Does correction of dose homogeneity improve the cosmetic outcome following radiotherapy in patients with early breast cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Cambridge Reseach Ethics Committee on 04/02/03, reference number 03/017

Study design
Interventional, phase III, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Patients are randomised to receive Intensity Modulated Radiation therapy (IMRT).
Control group will receive standard 2-dimensional radiation therapy.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Breast shrinkage following radiotherapy

Secondary outcome measures
1. Acute skin reactions
2. Clinical assessment of late cosmetic effect
3. Patients quality of life

Overall study start date
01/04/2003

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Age 18 years and above
2. Operable unilateral breast cancer (T1-3, N0-1, M0 at presentation)
3. Histological confirmation of invasive carcinoma
4. Complete macroscopic excision of tumour by breast conserving surgery
5. No history of contralateral breast cancer
6. Demonstration of off-axis dose inhomogeneities outside -5% and +7% of the prescribed dose using conventional 2-dimensional radiotherapy treatment plan
7. Patients consents to be part of the trial and availability for follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
375

Key exclusion criteria
1. Patients with advance or metastatic breast cancer
2. Patients who have had a mastectomy
3. Patients with bilateral breast cancer

4. Concomitant invasive malignancy (apart from Cervical Intra-epithelial Neoplasia [CIN] III uterine cervix and basal carcinoma of the skin), if other previous malignancies, must be disease-free for five years

Date of first enrolment
01/04/2003

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oncology Centre
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Trust Research and Development Department
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Addenbrookes Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Breast Cancer Campaign (London), grant reference number 2001:263 (UK)

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?
Results article	baseline characteristics and dosimetry results	01/07/2009		Yes	No
Other publications	prospective analysis study	01/01/2012		Yes	No