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Radiation dosimetry in determining complications and quality of life in women treated for breast-preserving surgery and radiotherapy

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC00049

Study information

Scientific Title
Radiation dosimetry in determining complications and quality of life in women treated for breast-preserving surgery and radiotherapy

Study objectives
Post-operative radiotherapy in women with early breast cancer accounts for more than 25% of NHS radiotherapy resource usage. Improvements in treatment accuracy for this important group of patients have lagged far behind technological developments applied routinely in patients with cancer at other anatomical sites. This has been a major contribution to unacceptably high rates of complications in some radiotherapy departments. The current proposal aims to test the clinical benefits of improved radiation dose distributions in the breast and ribcage of women prescribed radiotherapy after breast-preserving surgery for early stage cancer. The hypothesis is that these improvements will halve the risk of adverse events and improve functional status. Simple procedures for designing and manufacturing 3D breast tissue compensators will be tested against standard techniques in a randomised clinical trial. The benefits of reduced radiation morbidity using a combination of external assessments and patient self-assessments. The aim of this study is to test the clinical benefits of improved radiation dose distributions in the breast and ribcage of women prescribed radiotherapy after breast-preserving surgery for early stage cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
3D breast tissue compensators will be tested against standard techniques.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1996

Completion date
01/12/1998

Eligibility

Key inclusion criteria
Women with early breast cancer, histological confirmation of invasive carcinoma, breast-preserving surgery, brassiere cup size C or more, no previous malignancy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

Total final enrolment
240

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/1996

Date of final enrolment
01/12/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Marsden NHS Trust
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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	results	01/03/2007	31/10/2019	Yes	No