

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John Yarnold

Contact details
The Royal Marsden NHS Trust
Downs Road
Sutton
United Kingdom
SM2 5PT
-
abc@email.com

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

Results and Publications

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