

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/10/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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

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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?
<a href="#">Results article</a>	results	01/03/2007	31/10/2019	Yes	No