ISRCTN48733595 https://doi.org/10.1186/ISRCTN48733595

A randomised trial of custom-made compensators versus standard wedge compensators for breast radiotherapy

Submission date 15/10/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/10/2002	**Overall study status** Completed	
Last Edited 08/04/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
UKCCCR Register Co-ordinator
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NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Breast Dosimetry

Study information

Scientific Title
A randomised trial of custom-made compensators versus standard wedge compensators for breast radiotherapy

Study objectives
Not provided at time of registration

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
1. Radiotherapy with either custom-made compensators
2. Standard wedge compensators

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1997

Completion date
19/01/2000

Eligibility

Key inclusion criteria
1. Early breast cancer (T1-3a N0-1 M0)
2. Histological confirmation of invasive carcinoma
3. Breast-preserving surgery
4. Higher than average risk of radiation normal tissue changes due to large breast size or irregular breast shape
5. Radiotherapy to the breast +/- lymphatics
6. No previous malignancy
7. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1997

Date of final enrolment
19/01/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Institute of Cancer Research

Alternative Name(s)
Institute of Cancer Research - CIHR, CIHR Institute of Cancer Research, L'Institut du cancer, Institut du cancer, ICR - CIHR, ICR, IC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Royal Marsden Hospital

Funder Name
South East Thames Regional Health Authority

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