

Investigating the protocols for radiotherapy to the breast: an evaluation of treatment morbidity, accuracy and efficiency

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/02/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Study information

Scientific Title

Investigating the protocols for radiotherapy to the breast: an evaluation of treatment morbidity, accuracy and efficiency

Study objectives

The principal research questions:

1. Does a reduction in the central lung depth of a tangential breast field correspond to a clinically measurable difference in patient reported respiratory symptoms?
2. What are the treatment and patient related factors that influence patient reported respiratory symptoms?
3. Does the method of skin marking affect the accuracy and reproducibility of the radiotherapy treatment?
4. Does the method of skin marking affect patient reports of perceived body image.

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

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Patients that consent to participate are randomised to one of two lung depth groups and one of two skin marking categories.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Quality of life, assessed using EORTC QLQ C- 30 pre treatment and ten week post treatment
2. Treatment accuracy assessed by measuring radiation field placement in relation to the patient's' anatomy on three portal images taken during the treatment course. Measurements are compared with dimensions calculated during the patient's' initial treatment planning session.

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/01/1999

Completion date

12/01/2001

Eligibility**Key inclusion criteria**

All patients diagnosed with stage I and II breast cancer referred for adjuvant radiotherapy under three specialist breast oncologists (at Cookridge Hospital, Leeds)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

10/01/1999

Date of final enrolment

12/01/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cookridge Hospital

Leeds

United Kingdom

LS16 6QB

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 Northern and Yorkshire (UK) (ref: RRCC715F Probst)

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