ISRCTN34017998 https://doi.org/10.1186/ISRCTN34017998

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/02/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Heidi Probst

Contact details
Cookridge Hospital
Yorkshire Centre for Clinical Oncology
Hospital Lane
Leeds
United Kingdom
LS16 6QB
+44 (0)113 392 4104
HEIDIP@ulth.northy.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0461053544

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