ISRCTN84236905 https://doi.org/10.1186/ISRCTN84236905

Support, Positioning and Organ Registration during breast cancer Radiation Therapy: SuPPORT 4 All

Submission date
10/08/2011

Recruitment status
No longer recruiting

Registration date
27/09/2011

Overall study status
Completed

Last Edited
11/05/2016

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Women diagnosed with breast cancer undergo surgical removal of the tumour (lump) as first line treatment. When only the tumour is removed and the patient still has the rest of the breast, radiotherapy is given to reduce the chance of the cancer returning. Previously, radiotherapy to the whole breast was used for this, however, to minimize unwanted side effects, radiotherapy treatments have become more complex, to target only the area affected. It has become important to ensure accurate targeting of the breast within the radiotherapy beam. Currently there are no devices in use that will allow radiation therapists to position a patients breast accurately to target treatment. Poor targeting can lead to unwanted side effects. Furthermore, in most radiotherapy departments women undergoing breast radiotherapy lie on the treatment bed naked from the waist upwards while up to 4 staff (including men) adjust their position in preparation for treatment, which can cause stress in the patient. This study aims to develop a support bra that will allow accurate positioning of the breast on a day to day basis, which is acceptable to patients and helps to maintain modesty during treatment. The aim of this first phase is to identify the requirements of patients and staff for a support bra as well as testing a range of materials that could be used for this. The work undertaken in this phase will be followed by the development of a prototype (test product) that will then undergo testing before patients are able to test it.

Who can participate?
Members of staff who have experience of treating or planning radiotherapy for breast cancer and patients who have had a breast lump surgically removed (but still have the rest of the breast) and underwent radiotherapy for breast cancer. Patients were female and over the age of 18 years.

What does the study involve?
Patients will be asked to participate in a focus group with other patients to discuss their experience of radiotherapy and to give their views on what a support bra for radiotherapy should look like and how it could be designed. As part of the study patients will be asked to keep a personal journal about their experience during their radiotherapy treatment. Staff participants

will be asked to participate in one to one interviews to discuss their view of how a support bra should be designed. The radiotherapy treatment of participants will not be altered in any way.

What are the possible benefits and risks of participating?
This study is an opportunity to contribute to the development of a support bra that could improve the modesty of patients undergoing radiotherapy for breast cancer. There are no known risks associated with this study.

Where is the study run from?
The study was run from two radiotherapy centres in Sheffield and Leeds; Sheffield was the lead centre.

When is study starting and how long is it expected to run for?
This phase of the study started in August 2011 and ran until November 2011. Participants for this phase were recruited for 3 months from August 2011.

Who is funding the study?
Engineering and Physical Sciences Research Council

Who is the main contact?
Dr Heidi Probst
h.probst@shu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Heidi Probst

ORCID ID
http://orcid.org/0000-0003-0035-1946

Contact details
Centre of Health and Social Care Research
Collegiate Crescent Campus
36 Collegiate Crescent
Sheffield
United Kingdom
S10 2BP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10524

Study information

Scientific Title
Support, Positioning and Organ Registration during breast cancer Radiation Therapy: a Phase I study

Acronym
SuPPORT 4 All

Study objectives
There is evidence that immobilising the breast during radiotherapy is problematic. In particular, patients with large pendulous breasts are more difficult to position accurately for treatment than women with smaller breasts. Furthermore, an increase in the complexity of the radiotherapy set-up and a potential move towards partial breast irradiation necessitates improvement in breast reproducibility during adjuvant breast irradiation if patient outcomes are to be enhanced. This study aims to collect pre-clinical test data to identify the most appropriate method for immobilising and subsequently registering the patient position for breast treatment in order to provide sound evidence for, Phase II and III studies. The results of this study will inform the subsequent phases of the research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and The Humber Bradford NRES Committees, 05/05/2011, ref: 11/YH/0099

Study design
Non-randomised trial

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

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

The study follows the framework proposed by the Medical Research Council (MRC) for randomised controlled trials for complex interventions. This current phase reflects the pre-clinical (theory) and phase I (modelling) stages of the MRC framework. This phase includes a systematic review of the literature on available methods of immobilisation for breast irradiation, followed by qualitative data collection using focus groupswith breast cancer patients, one to one interviews with Oncologists and physicists and online blog discussions with therapy radiographers (radiation therapists). In addition, this phase includes physics testing of a range of materials on a linear accelerator to assess the suitability of materials to be used in the production of a prototype support device.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
The identification of an immobilisation method, an appropriate material for immobilisation and a suitable method for positional registration. The timepoint for this primary end point is November 2011 determined by evidence from the literature, the analysis of the qualitative data from stakeholders and the surface dose measurements taken from the material testing.

Secondary outcome measures
The development of a specification for the support bra. The timepoint for this endpoint is the end of November 2011 and will be determined by the analysis of the qualitative data from stakeholders.

Overall study start date
01/08/2011

Completion date
30/11/2011

Eligibility

Key inclusion criteria
The patient focus groups will include consenting patients that meet the following criteria:
1. Have completed (or completing) a course of adjuvant radiotherapy for early stage breast cancer
2. Have undergone a wide local excision
3. Able to speak and understand English (for the purposes of the focus groups it is important to include users from a range of socioeconomic and ethnic backgrounds, although having individuals who can speak and understand English will allow facilitation of discussions)
4. Female patients only, as the focus of this study is about immobilising mobile breast tissue following a wide local excision of a breast tumour
5. Age > 18 years

To gather product specification data from health professionals a purposive sample will be chosen from professionals who have specialist knowledge of breast irradiation. It is anticipated that this will consist of a range of professionals from the following disciplines:
1. Clinical Oncologists specialising in breast cancer

2. Radiation Therapists specialising in breast cancer
3. Dosimetrists or Medical Physicists with expertise in breast radiotherapy planning

Health care professional (HCP):
1. Completed basic training
2. Have recent experience of treating (or planning) breast cancer radiotherapy (i.e. in the last 3 years)
3. Minimum 18 years of age
4. Male or female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 41; UK Sample Size: 36; Description: Patients in the focus groups: 24 approximately

Key exclusion criteria
User focus groups:
1. Patients who have undergone a mastectomy
2. Patients with known metastasis
3. Patients unable to give informed consent

Date of first enrolment
01/08/2011

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Trust
Northern General Hospital
Herries Road

Sheffield, South Yorkshire
United Kingdom
S5 7AT

Study participating centre
Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds, West Yorkshire
United Kingdom
LS1 3EX

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council (EPSRC)

Alternative Name(s)

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results were presented in poster format at ESTRO conference. Unable to publish more as the bra design is confidential and development was ongoing.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/02/2014		Yes	No