ISRCTN18654225 https://doi.org/10.1186/ISRCTN18654225

Evaluation of tumour bed localisation and image-guided radiotherapy techniques for breast radiotherapy

Submission date
04/01/2006

Recruitment status
No longer recruiting

Registration date
03/08/2006

Overall study status
Completed

Last Edited
26/10/2018

Condition category
Cancer

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

Plain English Summary
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-a-new-way-of-locating-the-original-area-of-breast-cancer-after-surgery

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Coles

Contact details
Oncology Centre
Box 193
Addenbrookes Hospital
Hills road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 596182
charlotte.coles@addenbrookes.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of tumour bed localisation and image-guided radiotherapy techniques for breast radiotherapy

Acronym
Gold Seed Study

Study hypothesis
Develop an accurate and practical method of breast radiotherapy tumour bed localisation and tracking with Image-Guided Radiotherapy Techniques (IGRT), for implementation in oncology centres participating in the IMPORT HIGH Trial (ISRCTN47437448).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire research ethics committee (ref: 05/MRE03/74).

Study design
Interventional trial

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Condition
Breast cancer

Interventions
1. Imaging investigations (with radiation)
2. Additional portal imaging field and Computed Tomography (CT) scan
3. Insertion of gold breast markers at surgery

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Mean daily displacement in tumour bed centre of gravity expressed as three-dimensional co-ordinates.

Secondary outcome measures
1. Mean total displacement in tumour bed centre of gravity during a course of radiotherapy
2. Mean change in tumour bed volume
3. Intra- and inter-observer variability in tumour bed localisation

Overall study start date
01/11/2005

Overall study end date
31/07/2006

Eligibility

Participant inclusion criteria
1. Histological confirmation of invasive carcinoma
2. Operable unilateral breast cancer requiring breast conservation surgery
3. Patient unlikely to require chemotherapy based on biopsy results
4. Patient characteristics e.g. grade 1-2, aged more than 50 years, oestrogen receptor positive, tumours less than 4 cm

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Participant exclusion criteria
1. Patients requiring mastectomy: there will be no tumour bed to localise
2. Patients likely to require chemotherapy prior to radiotherapy: we wish to complete the study within six months and chemotherapy patients require six months of treatment before radiotherapy is started. In addition, there is considerable shrinkage of the tumour bed after six months as a consequence of seroma re-absorption and tissue re-modelling, thus the tumour bed would be more difficult to identify in this group of patients

Recruitment start date
01/11/2005

Recruitment end date
31/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oncology Centre
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Trust Research & Development
Box 146
Hills road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name

West Anglia Cancer Research Network (UK) (for payment of ISRCTN)

Funder Name
No external funding has been sought, any small additional costs will be funded by participating centres

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?
Plain English results				No	Yes
Results article	results	15/03/2011		Yes	No