

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

Submission date 04/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<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

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Contact details

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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 objectives

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

Health condition(s) or problem(s) studied

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

Completion date

31/07/2006

Eligibility**Key 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

Key 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

Date of first enrolment

01/11/2005

Date of final enrolment

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