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

Submission date	Recruitment status	[_] Prospectively registered
04/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2018	Cancer	

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
Mean daily displacement in tumour bed centre of gravity expressed as three-dimensional co-ordinates.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Oncology Centre
Cambridge

United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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

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