

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

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

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](mailto: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 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**

### 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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	15/03/2011		Yes	No