ISRCTN13672866 https://doi.org/10.1186/ISRCTN13672866

After mapping of the axilla: radiotherapy or surgery

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2019	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-radiotherapy-and-surgery-for-women-with-breast-cancer-which-has-spread-to-their-lymph-nodes

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00014612

Secondary identifying numbers
1424; EORTC 10981-22023

Study information

Scientific Title
A phase III study comparing a complete axillary lymph node dissection with radiotherapy to the axilla in sentinel biopsy positive patients

Acronym
EORTC 10981 (AMAROS)

Study objectives
After mapping of the axillary: radiotherapy or surgery, is a phase III study comparing a complete axillary lymph node dissection with radiotherapy to the axilla in sentinel biopsy positive patients, where-as sentinel node negative patients are followed for the end-points of the study as well.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-Centre Research Ethics Committee for Wales approved on the 22nd October 2005 (ref: 05 /MRE09/61)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Patients will be stratified by institution and will be randomised between complete axillary lymph node dissection and radiotherapy of the axilla.

Follow up length: 5 years
Study entry: single randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Axillary recurrence rate after 5 years.

Secondary outcome measures
1. Shoulder function analysis
2. Quality of life
3. Arm circumference

Node positive patients have annual examination and mammograms for 10 years. Quality of life questionnaire, arm circumference and shoulder function measurements measured at 1, 2, 3, 5 and 10 years.

Overall study start date
08/03/2007

Completion date
01/05/2010

Eligibility

Key inclusion criteria
1. Invasive breast cancer proven by core biopsy or 'triple diagnosis': clinical palpation concordant with malignancy, imaging (mammography or ultrasound) and tumour positive FNA cytology; diagnosis by excisional tumourectomy is allowed. Clinically occult invasive cancer should be proven by histology.
2. Tumour larger than 5 and smaller than 30 mm in its largest diameter, measured by mammography or ultrasound, only one tumour site (palpation, mammogram or ultrasound) in one breast: bilateral unifocal invasive breast cancer is allowed, (bilateral mammogram is mandatory)
3. Clinically negative axillary lymph nodes
4. Patient has to be fit to undergo any of the following treatments: SN-biopsy, axillary clearance, breast surgery, radiation therapy of the axilla
5. Before patient registration/randomisation, informed consent must be obtained according to ICH/EU GCP, and national/local regulations
6. Female, all ages considered
7. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
8. No metastatic disease (routine investigations are not required: symptoms should be investigated on indication)
9. No previous treatment of the axilla by surgery or radiotherapy
10. No previous treatment of cancer, except Basal Cell Carcinoma of the skin and in situ carcinoma of the cervix
11. No pregnancy

Participant type(s)
Patient

Age group
Other

Sex
Female

Target number of participants
Planned Sample Size: 4500; UK Sample Size: 600

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
08/03/2007

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cancer Trials Unit
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

Sponsor details
Avenue Mounierlaan, 83/11
Brussels
Belgium

1200
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eortc@eortc.be

Sponsor type
Research organisation

Website
http://www.eortc.be/

ROR
https://ror.org/034wxcc35

Funder(s)

Funder type
Research organisation

Funder Name
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

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	01/11/2014		Yes	No
Results article	results	01/06/2013	10/09/2019	Yes	No
Results article	results (Dutch)	01/11/2015	10/09/2019	Yes	No