

After mapping of the axilla: radiotherapy or surgery

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/09/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00014612

Protocol serial number

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

Study type(s)

Treatment

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(s)

Axillary recurrence rate after 5 years.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

Female

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)

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

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	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
Plain English results				No	Yes