

A multicentre randomised study of dose-intensive chemotherapy as primary treatment in a multimodality approach for locally advanced or inflammatory breast cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/08/2002	Overall study status Completed	☐ Protocol
Last Edited 10/03/2015	Condition category Cancer	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

C93

Study information

Scientific Title

A multicentre randomised study of dose-intensive chemotherapy as primary treatment in a multimodality approach for locally advanced or inflammatory breast cancer

Study objectives

Added 06/08/2009:

To determine the impact of intensive induction chemotherapy plus g-CSF in comparison to a standard regimen on time to distant metastases and overall survival in patients with locally advanced or inflammatory breast cancer.

As of 06/08/2009 this trial has been updated. All updates can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

1. Regimen A: Chemotherapy with cyclophosphamide, epirubicin and 5-fluorouracil (CEF) repeated every four weeks for six courses, unless there is earlier progression, plus oral trimethoprim-sulphamethoxazole (TMP + SMZ) 480 mg twice daily for the duration of chemotherapy.
2. Regimen B: High dose intensity chemotherapy with etoposide and cyclophosphamide plus Granulocyte-Colony Stimulating Factor (G-CSF) repeated every two weeks for six cycles, unless there is earlier progression. If following chemotherapy there is a response or stable disease then patients commence locoregional treatment, either surgery, radiotherapy or both. Following locoregional treatment patients receive maintenance hormonotherapy, tamoxifen 20 mg daily until relapse.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cyclophosphamide, epirubicin, 5-fluorouracil, etoposide, granulocyte-colony stimulating factor (G-CSF), trimethoprim-sulphamethoxazole and tamoxifen

Primary outcome(s)

Added 06/08/2009:

1. Response rate
2. Survival
3. Quality of life

Key secondary outcome(s)

Not provided at time of registration

Completion date

04/04/1996

Eligibility

Key inclusion criteria

1. Female patients with histologically confirmed breast cancer in the following subgroups:
 - 1.1. T4 Nx
 - 1.2. Any N2 or N3, M0
 - 1.3. Clinically inflammatory breast carcinoma defined as redness over at least one-third of the breast
 - 1.4. M0 except for ipsilateral supraclavicular nodes
2. No evidence of tumour spread other than as defined above
3. No previous surgical, systemic or radiation treatment for breast cancer, other than biopsy for confirmation of the diagnosis
4. World Health Organisation (WHO) performance status zero to two
5. Adequate renal, hepatic and haematological function
6. No previous or concomitant malignancy except adequately treated squamous or basal cell carcinoma of the skin, or adequately treated cone-biopsied in situ carcinoma of the cervix uteri
7. No significant cardiac disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/1996

Date of final enrolment

04/04/1996

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

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

Alternative Name(s)

EORTC

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Belgium

Funder Name

National Cancer Institute of Canada (NCIC) (Canada)

Funder Name

Swiss Institute for Applied Cancer Research (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration