

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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/03/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

Added 06/08/2009:

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1996

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

400 (added 06/08/2009)

**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**

England

United Kingdom

**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)

**Sponsor details**

83, Avenue E. Mounier

Bte 11

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B-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

**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**

**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