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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 [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/03/2015	**Condition category** Cancer	[_] 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
- - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
Brussels
Belgium
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