An international randomized trial in Locally Advanced Breast Cancer comparing 6 courses of neo-adjuvant doxorubicin and cyclophosphamide plus GM-CSF or G-CSF with a split-course administration of 3 neo-adjuvant and 3 adjuvant cycles including either GM-CSF or G-CSF.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27543

Source
NTR

Brief title
Spinoza

Health condition

Locally advanced breast cancer.

Sponsors and support

Primary sponsor: VU medisch centrum
Source(s) of monetary or material Support: VU medisch centrum

Intervention

Outcome measures

Primary outcome

Recurrence of disease or all cause mortality (whichever comes first).

Secondary outcome

1. Disease-free survival;

2. Overall survival;

3. Response rate.

Study description

Background summary

The study has ceased due to a stop of procedure GM-CSF by the manufacturer.

De studie is gestaakt vanwege stop procedure GM-CSF door de fabrikant.

Study objective

To detect any effect on disease-free survival from treatment with 3 neo-adjuvant and 3 adjuvant chemotherapy cycles (standard treatment) versus 6 neo-adjuvant chemotherapy cycles
To study the effect of GM-CSF versus G-CSF on potential effect on disease-free survival.

Study design

N/A

Intervention

Arm A:
6 neoadjuvant cycles doxorubicin and cyclophosphamide;

Arm B:
3 neoadjuvant + 3 adjuvant cycles doxorubicin and cyclophosphamideIn each study arm 50% of the patients will receive GM-CSF(250 ìg/m2 daily sc day 2-12) and 50% G-CSF (5 ìg/kg daily sc day 2-12) in a randomised fashion. Doxorubicin and cyclophosphamide are administered on day 1 every 3 weeks.
Doses of doxorubicin :
Cycle 1 90 mg/m2;
Cycles 2-3 82.5 mg/m2;
Cycles 4-C6 75 mg/m2
Doses of cyclophosphamide:
Cycle 1 1000 mg/m2;
Cycles 2-3 875 mg/m2;
Cycles 4-6 750 mg/m2

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven breast cancer;

2. Locally advanced breast cancer: stage IIB with a primary breast tumor > 5 cm ©ª (T3 tumor), IIIA or IIIB according to the AJCC criteria;

3. Adequate hematological, renal and hepatic functions (WBC ¡Ã3.0 x 109/l, platelets ¡Ã 150 x

109/l); normal serum bilirubin; normal ASAT (SGOT), ALAT (SGPT) and AF, normal serum creatinine;

4. Age > 18 and < 65 years;

5. Performance status (Karnofsky index ¡Ã 80% or WHO ¡Â grade 1);

6. Written informed consent.

Exclusion criteria

1. Pregnant, or lactating patients. Patients of childbearing potential must use adequate contraception;

2. Distant metastases;

3. Clinically evident infection or other serious underlying medical condition not compatible with studies entry, eg. Uncontrolled hypertension, cardiac disease (ischaemia, previous myocardial infarction) within 6 months prior to treatment;
4. LVEF < 50%;

5. History of significant neurological or psychiatric disorders including dementia that would prohibit the understanding and giving of informed consent;

6. Prior history of malignancy other than adequately treated basal cell carcinoma of the skin or in sity carcinoma of the cervix, or current other malignancy;

7. Bilateral breast cancer;

8. Previous chemotherapy, radiotherapy or hormone therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-02-1999
Enrollment:	720
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL136
NTR-old	NTR170
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A