Three arm randomized parallel phase II/III study evaluating the efficacy and safety of the combinations Epirubicin and Taxotere (ET), Taxotere and Navelbine (TN) and Navelbine and Epirubicin (EN) as first line therapy in pat. with metastatic breast cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29407

Source
Nationaal Trial Register

Brief title
ETN studie

Health condition

Metastic breast cancer.

Sponsors and support

Primary sponsor: VU medical center.
Source(s) of monetary or material Support: Aventis
Pierre Fabre
Amgen
Pfizer

VU medical center

Intervention

Outcome measures

Primary outcome

Time to progression, response rate.

Secondary outcome

Toxicity profile, feasibility.

Study description

Background summary

N/A

Study objective

Primary objectives:

To assess the efficacy in terms of response rate of the combinations Epirubicin and Taxotere (ET), Taxotere and Navelbine (TN) and Navelbine and Epiribicin (EN).

Secondary objectives:

To determine: Progression free survival, Toxicity profiles.

Study design

N/A

Intervention

Arm A: Epirubicin 75 mg/m2, day 1 and docetaxel 60 mg/m2 day 1;

Arm B: Vinorelbine 20 mg/m2 day 1+8 and docetaxel 60 mg/m2 day 8 (closed January 2003);

Arm C: Epirubicin 75 mg/m2 day 1 and vinorelbine 25 mg/m2 days 1 and 8One course consists of 21 days. Cycle is repeated every 3 weeks, for a maximum of 6 cycles.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven breast cancer at first diagnosis. At study entry histological or cytological proof of metastasis is required in case of a single metastatic target lesion.
Female metastatic breast cancer patients
Measurable disease or evaluable disease (bone metastases only allowed).

2. Previous chemotherapy:

Adjuvant: Patients may have had adjuvant and/or neoadjuvant chemotherapy but no more than 240 mg/m² cumulative dose of prior doxorubicin or no more than 450 mg/m² of Epirubicin. Taxanes in adjuvant setting are allowed. However, there must be at least 12 months interval between the end of (neo-)adjuvant chemotherapy and protocol entry. This interval is not required for patients who received non-anthracycline/non-taxane adjuvant and/or neoadjuvant chemotherapy. No previous chemotherapy for metastatic breast cancer is allowed.

3. Previous hormonal treatment:

Previous hormonal treatment is allowed provided discontinuation >4 weeks before start of study treatment.

4. Previous radiation:

Previous radiation therapy may have been given provided it is not the only site to assess response.

5. Age > 18 and < 70 years.

6. WHO performance status 0, 1 or 2.

7. Laboratory requirements:

a. Hematology : White blood cell count > 3.0 x109/l (if WBC < 3.0 x 109/l, Neutrophils should be > 1.5 x 109/l)Platelets > 100 x 109/lHemoglobin > 10 g/dl (> 6.2 mmol/L).

b. Hepatic functionTotal bilirubin < 1.00 times the upper-normal limits of the institutional normal values.ASAT (SGOT) and/or ALAT (SGPT) < 2.5 UNL, alkaline phosphatase < 5 UNL (unless bone metastasis are present in the absence of any liver disorders). NB: Patients with ASAT and/or ALAT > 1,5 UNL associated with alkaline phosphatase > 2.5 UNL are not eligible for study.

c. Renal function : Serum creatinine < 80 µmol/llf serum creatinine > 80 µmol/l, calculated creatinine clearance (Cockroft Gould) should be > 60 ml/min.

8. Normal left ventricular ejection fraction (LVEF) or superior to the lower limits of the institution (determined by either MUGA scan or ultrasound methods).

9. Patients must be accessible for treatment and follow-up.

10. Measurability of the disease and evaluation of response according to RECIST criteria.

11. Complete initial work-up within 3 weeks prior to first infusion.

12. Written informed consent.

Exclusion criteria

1. Prior chemotherapy for metastatic disease.

2. Locally advanced inoperable breast cancer (Stage III B) as only manifestation of the disease.

3. Non-measurable disease.

4. Pregnant or lactating women or women of childbearing potential not using adequate contraception.

5. History of prior malignancies (other than non melanoma skin cancer or excised cervical carcinoma in situ).

6. Clinical evidence of cerebral metastasis.

7. Symptomatic peripheral neuropathy > grade 2 according to the NCI Common Toxicity Criteria.

8. WHO PS>2.

9. Concurrent treatment with other experimental drugs. Participation in another clinical trial with any investigational drug within 30 days prior to study screening.

10. Concurrent treatment with any other anti-cancer therapy except for concomitant treatment with bisphosphonates, provided that bone metastases are not the only evaluable lesions for response to therapy (see measurability of disease and evaluation of response).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2001
Enrollment:	111
Type:	Actual

Ethics review

Positive opinion

Date:	26-10-2005
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	NL432
NTR-old	NTR472
Other	: N/A
ISRCTN	ISRCTN33132357

Study results

Summary results
N/A