

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 patients with metastatic breast cancer

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 03/07/2009	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

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Additional identifiers

Protocol serial number

NTR472

Study information

Scientific Title**Acronym**

ETN study

Study objectives

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 Epirubicin (EN).
Secondary objectives: To determine progression free survival and toxicity profiles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local media ethics committee

Primary study design

Interventional

Study design

multicentre, randomised, active controlled, parallel group study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

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 8.

One course consists of 21 days. Cycle is repeated every 3 weeks, for a maximum of 6 cycles.

Intervention Type

Drug

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

epirubicin, docetaxel (Taxotere®), vinorelbine (Navelbine®)

Primary outcome(s)

1. Time to progression
2. Response rate

Key secondary outcome(s)

1. Toxicity profile
2. Feasibility

Completion date

01/12/2005

Eligibility

Key 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.
2. Female metastatic breast cancer patients
3. Measurable disease or evaluable disease (bone metastases only allowed)
4. 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.
5. Previous hormonal treatment: Previous hormonal treatment is allowed provided discontinuation >4 weeks before start of study treatment
6. Previous radiation: Previous radiation therapy may have been given provided it is not the only site to assess response
7. Age >18 and <70 years
8. WHO performance status 0, 1 or 2
9. Laboratory requirements:
 - a. Hematology: White blood cell count >3.0 x 10⁹/l (if WBC <3.0 x 10⁹/l, Neutrophils should be >1.5 x 10⁹/l), Platelets >100 x 10⁹/l, Hemoglobin >10 g/dl (>6.2 mmol/l)
 - b. Hepatic function: Total bilirubin <1.00 times the upper-normal limits (UNL) 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 umol/l. If serum creatinine >80 umol/l, calculated creatinine clearance (Cockcroft Gould) should be >60 ml/min
10. Normal left ventricular ejection fraction (LVEF) or superior to the lower limits of the institution (determined by either MUGA scan or ultrasound methods)
11. Patients must be accessible for treatment and follow-up
12. Measurability of the disease and evaluation of response according to RECIST criteria
13. Complete initial work-up within 3 weeks prior to first infusion
14. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key 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
10. Participation in another clinical trial with any investigational drug within 30 days prior to study screening
11. 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)

Date of first enrolment

01/04/2001

Date of final enrolment

01/12/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Center (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)**Funder type**

Industry

Funder Name

Amgen (Netherlands)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Pfizer (Netherlands)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Pierre Fabre (France)

Funder Name

Sanofi-Aventis (France)

Funder Name

VU University Medical Center (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary