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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Bron

NTR

Verkorte titel

ETN studie

Aandoening

Metastic breast cancer.

Ondersteuning

Primaire sponsor :	VU medical center.
Overige ondersteuning :	Aventis Pierre Fabre Amgen Pfizer VU medical center

Onderzoeksproduct en/of interventie

Geen registraties gevonden.

Uitkomstmaten

Primaire uitkomstmaten

Time to progression, response rate.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blindering :	Open / niet geblindeerd
Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving gestopt
(Verwachte) startdatum :	01-04-2001
Aantal proefpersonen :	111
Type :	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum :	26-10-2005
Soort :	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL432
NTR-old	NTR472
Ander register	: N/A
ISRCTN	ISRCTN33132357

Resultaten

Samenvatting resultaten

N/A