A randomized, open-label phase III study of first line chemotherapy in older metastatic breast cancer patients, comparing intravenous pegylated liposomal doxorubicin with oral capecitabine; and the incorporation of a complete geriatric assessment.

Gepubliceerd: 09-02-2007 Laatst bijgewerkt: 18-08-2022

This trial aims to demonstrate the superiority of PEG doxorubicin (with 3 months) over capecitabine as first line chemotherapy in patients with metastatic breast cancer.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25134

Bron
NTR

Verkorte titel
OMEGA

Aandoening

Metastatic breastcancer in elderly patients.
Gemetastaseerd borstkanker bij oudere patienten.

Ondersteuning

Primaire sponsor: Borstkanker Onderzoeks Groep (BOOG)
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To compare the progression free survival (PFS) in elderly patients (> 65 years of age) with metastatic breast cancer treated with either PEG doxo or capecitabine as first line chemotherapy. Kaplan-Meier method will be used to estimate the distribution of overall time to disease progression (TTP) for each treatment and the two-sided log-rank test with significance level of 0.05 will be used to compare the TTP distribution between the two treatments.

Toelichting onderzoek

Achtergrond van het onderzoek

Female patients with metastatic breast cancer, being 65 years or older, who are eligible for first line chemotherapy will be randomized between pegylated liposomal doxorubicin (PEG doxo, 45 mg/m2) (given intravenously, each 28 days), and capecitabine (2000 mg/m2, days 1-14, to be repeated every 21 days).
Questionnaires regarding Quality of Life (QoL) and a geriatric assessment tool (GA) will be incorporated to further investigate the contribution and role of this type of assessments aiming to improve the clinical evaluation of the condition and/or frailty of the individual patient and quality of life during chemotherapy in elderly metastatic breast cancer patients.

Doel van het onderzoek

This trial aims to demonstrate the superiority of PEG doxorubicin (with 3 months) over capecitabine as first line chemotherapy in patients with metastatic breast cancer.

Onderzoeksproduct en/of interventie

6 cycles of intravenous pegylated liposomal doxorubicin (q 4 weeks) compared to 8 cycles of oral capecitabine (q 3 weeks).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female patients with metastatic breast cancer, being eligible for first line chemotherapy;
2. Age > 65 years;
3. Non-measurable (evaluable) or measurable disease (according to RECIST criteria). In case of evaluable (non-measurable) disease, the presence of an increased tumormarker (either Ca15.3, Ca125, CEA, whatever is increased) is obligatory;
4. ECOG performance score of 0 – 2
5. May be HER-2/neu positive or negative
6. Adequate bone marrow function, acceptable renal function and acceptable liver functions
7. Normal baseline LVEF by MUGA scan according to the institutional limits, no prior history of myocardial infarction within < 6 months, no cardiac insufficiency (NYHA Class II or greater), no clinical evidence of congestive heart failure (CHF) or myocardial infarct (MI) within less than six months

8. Written informed consent
9. Patients being willing and able to complete study questionnaires in the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No anthracyclin-resistant disease (defined as development of locally recurrent or metastatic disease while on adjuvant anthracycline therapy, or relapse within 12 months after completion of anthracycline therapy) and adjuvant cumulative anthracycline dose (if given in the adjuvant setting) of < 240 mg/m2 of doxorubicin (or < 450 mg/m2 of epirubicin);
2. Evidence of MBC in the central nervous system, unless previously treated and being asymptomatic/controlled for at least 3 months;
3. No current or previous chemotherapy for metastatic breast cancer (unless received in the adjuvant setting; patient may also have received hormonal and/or trastuzumab therapy for metastatic disease, as long as this therapy has been stopped for over 2 weeks);
4. No other malignancy within the previous 5 years (except adequately treated in situ carcinoma of cervix, or basal cell carcinoma);
5. No abuse of drugs, alcohol, pharmaceuticals, competing with adequate compliance in this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-02-2007
Aantal proefpersonen:	154
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-02-2007
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	NL882
NTR-old	NTR897
Ander register	: 2006-02
ISRCTN	ISRCTN11114726

Resultaten

Samenvatting resultaten
N/A