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.

No registrations found.

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

Summary

ID

NL-OMON25134

Source
NTR

Brief title
OMEGA

Health condition

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

Sponsors and support

Primary sponsor: Borstkanker Onderzoeks Groep (BOOG)
Plesmanlaan 125
1066 CX Amsterdam
00-31-(0)20-346 2547

boog@ikca.nl
Source(s) of monetary or material Support: Borstkanker Onderzoeks Groep (BOOG)
Plesmanlaan 125
1066 CX Amsterdam
00-31-(0)20-346 2547
boog@ikca.nl

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To compare the objective response rates (CR and PR, according to RECIST criteria) between the two treatment regimens, given as first line chemotherapy in MBC in elderly patients;
2. To compare the rate of clinical benefit (CR, PR, and SD over 24 weeks);
3. To compare the overall survival between the two treatment regimens;
4. To evaluate the relation of response and toxicity of the respective chemotherapy regimen with co-morbidity and co-medication.

Study description

Background summary

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.

Study objective

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.

Intervention

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

Contacts

Public
Plesmanlaan 125
Borstkanker Onderzoek Groep (BOOG)
Amsterdam 1066 CX
The Netherlands
+31-(0)20-346 2547
Scientific
Plesmanlaan 125
Borstkanker Onderzoek Groep (BOOG)
Amsterdam 1066 CX
The Netherlands
+31-(0)20-346 2547

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2007
Enrollment:	154
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2007
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	NL882
NTR-old	NTR897
Other	: 2006-02
ISRCTN	ISRCTN11114726

Study results

Summary results
N/A