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A randomised, 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

Submission date 07/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/03/2007	**Overall study status** Completed	
Last Edited 12/02/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ikcnet.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2006-002046-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006-02

Study information

Scientific Title

Acronym
OMEGA

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics committee (Medisch Ethische Toetsingscommissie [METC] Noord-Holland) on the 14/07/2006 (ref: METC-registration M06-015, CCMO-registration P06.0785L).

Study design
Randomised, open labelled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Metastatic breast cancer in elderly patients

Interventions
Six cycles of intravenous pegylated liposomal doxorubicin (45 mg/m^2 every four weeks) compared to eight cycles of oral capecitabine (2000 mg/m^2, days one to 14 every three weeks). Questionnaires regarding Quality of Life (QoL) and a Geriatric Assessment tool (GA) will also be incorporated.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Pegylated liposomal doxorubicin and capecitabine

Primary outcome measure
To compare the Progression Free Survival (PFS) in elderly patients (greater than 65 years of age) with metastatic breast cancer treated with either PEG doxorubicin or capecitabine as first line chemotherapy. The 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 measures
1. To compare the objective response rates (Complete Response [CR] and Partial Response [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 Stable Disease [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

Overall study start date
15/02/2007

Completion date
15/08/2008

Eligibility

Key inclusion criteria
1. Female patients with metastatic breast cancer, being eligible for first line chemotherapy
2. Aged greater than 65 years
3. Non-measurable (evaluable) or measurable disease (according to Response Evaluation Criteria in Solid Tumours [RECIST] criteria). In case of evaluable (non-measurable) disease, the presence of an increased tumour marker (either Cancer antigen 15.3 [Ca15.3], Cancer antigen-125 [Ca125], Carcinoembryonic Antigen [CEA], whatever is increased) is obligatory
4. European Cooperative Oncology Group (ECOG) performance score of zero to two

5. May be Human Epidermal growth factor Receptor 2 (HER-2/neu) positive or negative
6. Adequate bone marrow function, acceptable renal function and acceptable liver functions
7. Normal baseline Left Ventricular Ejection Fraction (LVEF) by Multiple Gated Acquisition (MUGA) scan according to the institutional limits, no prior history of myocardial infarction within less than six months, no cardiac insufficiency (New York Heart Association [NYHA] Class II or greater), no clinical evidence of Congestive Heart Failure (CHF) or Myocardial Infarction (MI) within less than six months
8. Written informed consent
9. Patients being willing and able to complete study questionnaires in the Dutch language

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
154

Key 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 less than 240 mg/m^2 of doxorubicin (or less than 450 mg/m^2 of epirubicin)
2. Evidence of Metastatic Breast Cancer (MBC) in the central nervous system, unless previously treated and being asymptomatic/controlled for at least three 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 two weeks)
4. No other malignancy within the previous five 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

Date of first enrolment
15/02/2007

Date of final enrolment
15/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre

Breast Cancer Study Group (Borstkanker Onderzoeks Groep [BOOG])
Amsterdam
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Sponsor information

Organisation
Breast Cancer Study Group (Borstkanker Onderzoeks Groep [BOOG]) (The Netherlands)

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Sponsor type
Research organisation

ROR
https://ror.org/04cr37s66

Funder(s)

Funder type
Research organisation

Funder Name
Breast Cancer Study Group (Borstkanker Onderzoeks Groep [BOOG]) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No