ISRCTN13770586 https://doi.org/10.1186/ISRCTN13770586

Open label, comparative, randomised, multicentre study of trastuzumab given with docetaxel versus sequential single agent therapy with trastuzumab followed by docetaxel as first-line treatment for Her2neu+++ metastatic breast cancer patients

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
14/11/2008

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
NTR308

Study information

Scientific Title

Acronym
HERTAX, BOOG 2002-02

Study objectives
Although combined treatment will probably lead to higher response rates, sequential treatment may result in a similar time to progression in the presence of less side effects and a better quality of life in a significant number of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, open-label, randomised, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Arm A: combination of trastuzumab and docetaxel
Arm B: trastuzumab followed by docetaxel

Trastuzumab:
Loading dose of 4 mg/kg intravenous (IV) on day 1, administered as 90-minute infusion, followed by a weekly dose of 2 mg/kg

Docetaxel:
TXT 100 mg/m2 IV infusion over one hour repeated in cycles, every 3 weeks for 6 cycles.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trastuzumab, docetaxel

Primary outcome(s)
Progression free survival of total sequential versus combined treatment.

Key secondary outcome(s))
Response rate and overall survival.

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Histologically documented invasive adenocarcinoma of the breast
2. Women with previously chemotherapeutically untreated metastatic breast cancer with HER2neu over expression (defined as 3+ IHC by DAKO HercepTest)
3. Patients having previously received adjuvant treatment with an anthracycline/anthraquinone (maximum cumulative dose: doxorubicin 360 mg/m^2, epirubicin 750 mg/m^2 or equivalent dose of other anthracycline/anthraquinone)
4. Patients over the age of 18; Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2 and life expectancy greater than 12 weeks
5. Patients with evaluable disease or patients having at least one measurable target outside previously irradiated field
6. Adequate bone marrow, hepatic and renal functions as evidenced by the following:
6.1. Haemoglobin greater than 6 mmol/l and no blood transfusion within the previous 2 weeks
6.2. White Blood Cell (WBC) count greater than 3.0 x 10^9 cells/l and neutrophils greater than 1.5 x 10^9 cells/l
6.3. Platelets count greater than 100 x 10^9 cells/l
6.4. No evidence of myelodysplastic syndrome or abnormal bone marrow reserve
6.5. Creatinine less than 1.5 upper normal limit (UNL) or creatinine clearance greater than 60 ml /min
6.6. Total bilirubin less than 1 x UNL
6.7. Aspartate aminotransferase (ASAT) (serum glutamic oxaloacetic transaminase [SGOT]) and /or alanine aminotransferase (ALAT) (serum glutamic pyruvic transaminase [SGPT]) less than 2.5 x UNL
6.8. Alkaline phosphatase less than 5 x UNL
6.9. ASAT and/or ALAT less than 1.5 x UNL in combination with elevated alkaline phosphatase less than 2.5 x UNL
7. Previous radiotherapy is allowed if end of radiotherapy (RT) more than 14 days prior to study entry, in case RT was given on relevant areas
8. Patient has fully recovered from all acute toxic effects
9. Normal cardiac function with left ventricular ejection fraction (LVEF) by echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA) greater than 50% or within UNL of the institution
10. Written informed consent and accessible for treatment and follow up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Operable local relapse alone after conservative treatment or contra-lateral tumour (mastitis or inoperable local recurrence is acceptable for inclusion)
2. Pregnant or lactating women (females of childbearing potential must use adequate contraception)
3. History or presence of brain or leptomeningeal metastases
4. Current peripheral neuropathy less than National Cancer Institute (NCI) grade 2
5. Other prior malignancies, except for cured non-melanoma skin cancer, curatively treated in situ carcinoma of the cervix
6. Other serious illness or medical conditions: cardiac insufficiency (New York Heart Association [NYHA] III or IV), myocardial infarction within previous 6 months, unstable angina pectoris, uncontrolled arrhythmia at time of inclusion
7. Patients with severe dyspnoea at rest due to complications of advanced malignancy or requiring supplementary oxygen therapy
8. Clinically significant active infections
9. Poorly controlled diabetes mellitus
10. Uncontrolled hypertension
11. Active peptic ulcer or other contraindication to high dose of corticosteroid therapy such as herpes zoster, cirrhosis
12. History of allergy to drugs containing polysorbate 20, or the excipient TWEEN 80
13. Patient with a history of a psychological illness or condition such as to interfere with the patients ability to understand the requirements of the study
14. Patients who had received an investigational new drug within the last 30 days
15. Patients having received prior therapy with taxoids or anti-HER2 therapies

Date of first enrolment
01/02/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus Medical Centre
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation
Breast Cancer Study Group (BOOG) (The Netherlands)

ROR
https://ror.org/04cr37s66

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV (The Netherlands)

Funder Name
Sanofi-Aventis (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration