Open label, comparative, randomized, multicenter, 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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26229

Source
NTR

Brief title
HERTAX, BOOG 2002-02

Health condition

Breast cancer patients with metastases with HER2neu overexpression (3+ assessed by IHC DAKO HercepTest), previously untreated by chemotherapy, except for neoadjuvant or adjuvant (non-taxane containing) chemotherapy.

Sponsors and support

Primary sponsor: BOOG
Source(s) of monetary or material Support: SanofiAventis
Roche

Intervention

Outcome measures

Primary outcome

Progression free survival of total sequential versus combined treatment.

Secondary outcome

Response Rate and Overall Survival.

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

Arm A: Comb. of trastuzumab + docetaxel;

Arm B: Trastuzumab followed by docetaxel.

Trastuzumab:

Loading dose of 4 mg/kg 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically documented invasive adenocarcinoma of the breast;

2. Women with previously chemotherapeutically untreated metastatic breast cancer with HER2neu overexpression (defined as 3+ IHC by DAKO HercepTest);

3. Patients having previously received adjuvant treatment with an anthracycline/ anthraquinone (maximum cumulative dose:
doxorubicin 360 mg/m2, epirubicin 750 mg/m2 or equivalent dose of other anthracycline/anthraquinone);

4. Patients over the age of 18;
ECOG performance status < = 2 and life expectancy >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;

7. Hemoglobin > 6 mmol / l and no blood transfusion within the previous 2 weeks;

8. WBC count > 3.0 x 109 cells/l and neutrophils >1.5 x 109 cells/l;

9. Platelets count > 100 x 109 cells/l;

10. No evidence of myelodysplastic syndrome or abnormal bone marrow reserve;

11. Creatinine < 1.5 upper normal limit (UNL) or creatinine clearance > 60 ml / min;

12. Total bilirubin < 1 x UNL;

13. ASAT (SGOT) and/or ALAT (SGPT) <2.5 x UNL;

14. Alkaline phosphatase < 5 x UNL;

15. ASAT and/or ALAT< 1.5 x UNL in combination with elevated alkaline phosphatase < 2.5 x UNL;

16. Previous radiotherapy is allowed if :
End of radiotherapy more than 14 days prior to study entry, in case RT was given on relevant areas;

17. Patient has fully recovered from all acute toxic effects;

18. Normal Cardiac Function with LVEF by ECHO or MUGA > 50% or within UNL of the institution;

19. Written informed consent and accessible for treatment and follow up.

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
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 condition:

Cardiac insufficiency (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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2003

Enrollment:	100
Type:	Actual

Ethics review

Positive opinion Date:	09-09-2005
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	NL270
NTR-old	NTR308
Other	: N/A
ISRCTN	ISRCTN13770586

Study results

Summary results
N/A