Open label randomized phase III study of weekly docetaxel and docetaxel every 3 weeks in patients with metastatic breast cancer, resistant to prior chemotherapy

No registrations found.

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

Summary

ID

NL-OMON23238

Source
NTR

Brief title
TAX 613

Health condition

breast cancer, metastatic, docetaxel; weekly regimen; tolerability; dose reduction; dose delay; quality of life;

Sponsors and support

Primary sponsor: Sanofi-Aventis
Source(s) of monetary or material Support: Sanofi-Aventis

Intervention

Outcome measures

Primary outcome

Primary endpoints:

Compare the overall safety profile in both arms : Assess the impact of differences in toxicity profiles on the incidence of dose reduction or dose delay due to grade III-IV toxicities during treatment of patients with pre-treated metastatic breast cancer with Taxotere in a weekly or a 3 weekly schedule

Secondary outcome

Secondary endpoints:

A. Evaluate efficacy criteria in the two arms:

- Time to progression

- Response rate

- Overall survival

B. Assess Quality of Life in both arms

Study description

Study objective

Compare the overall safety profile in both arms : Assess the impact of differences in toxicity profiles on the incidence of dose reduction or dose delay due to grade III-IV toxicities during treatment of patients with pre-treated metastatic breast cancer with Taxotere in a weekly or a 3 weekly schedule

Study design

Continious SAE monitoring

. The incidence of febrile neutropenia (% of patients) in the three-weekly schedule is estimated to be 15%, if it does not exceed 5% in the weekly schedule, this is considered clinically significant. Likewise, when estimating the percentage of patients treated every 3 weeks requiring dose reduction for any grade 3 or 4 toxicity at 25%, no more than 10% should require dose reduction in the weekly schedule.

Intervention

Docetaxel 100 mg/m2 q 3 wks vs

docetaxel 35 mg/m2 weekly x6 q 8 wks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically or cytologically proven breast adenocarcinoma

2. Measurable disease

3. Metastatic progressive breast cancer

4. Previous therapy: anthracycline containing adjuvant and/or first line therapy, unless clear contraindications for anthracycline treatments. No more than 1 line of chemotherapy for metastatic disease

5. Radiotherapy is allowed, no minimum time interval between the end of radiotherapy and study entry , however the irradiated lesion must not be the only lesion to evaluate response

6. Performance status ECOG < 2

7. Adequate liver function defined by:

Single abnormalities :

 Total bilirubine < upper normal limits

 Transaminases < 3.5x upper normal limits

 Alkaline phosphatase < 6x upper normal limits

Combined abnormalities :

 If transaminase levels are between 1.5x and 3,5 x upper normal limits and Alkaline phosphatase is between 2.5x and 6x upper normal limits, starting dosage should be reduced with 25%

 NOTE : patients with transaminases >3,5 x ULN associated with alkaline phosphatase >6x ULN are not eligible for study

8. Written informed consent given

9. Age >18 years

10. Compliance with follow up requirements

Exclusion criteria

1. ECOG > 2

2. Prior exposure to taxanes for metastatic disease.

3. Patient who received two or more lines of prior chemotherapy for metastatic disease

4. Inadequate bone marrow function:

 neutrophils < 1.5 x 109/L

 platelets <100 x 109/L

5. Inadequate liver function
defined by:

 Total bilirubin > UNL

6. Concurrent severe and/or co-morbid medical condition.

7. Concurrent treatment with other experimental drugs or clinical trials.

8. Definite contraindications for the use of corticosteroïds.

9. Pregnant or lactating women.

10. Symptomatic peripheral neuropathy > NCIC-CTC grade II

11. Hormonal treatment (prior hormonal treatment allowed)

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):	01-02-2001
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	13-10-2008
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	NL1445
NTR-old	NTR1506
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A