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-OMON21712

Source
NTR

Brief title
TAX 613

Health condition

Metastatic or advanced breast cancer, second line chemotherapy

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. PFS;

2. TTF.

Secondary outcome

OS.

Study description

Background summary

Weekly taxotere vs 3-weekly taxotere, compare Side effects and anti-tumor activity.

Study objective

Is docetaxel weekly as effective and less toxic than the same dose given 3-weekly.

Study design

> 50% participants deceased.

Intervention

Two different regimens.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically or cytologically proven breast adenocarcinoma;

2. Evaluable or measurable disease according to RECIST criteria;

3. Metastatic progressive breast cancer;

4. 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:

A. Single abnormalities:

- Total bilirubin < upper normal limit;

- Transaminases < 3.5x upper normal limits;

- Alkaline phosphatase < 6x upper normal limit.

B. 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 ASAT/ALAT >3,5 x ULN associated with ALP>6x ULN are not eligible for study.

8. Written informed consent given;

9. Age >18 years.

• 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:

A. Neutrophils < 1.5 x 109/L;

B. Platelets <100 x 109/L.

5. Inadequate liver function defined by:

A. 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 > NCI-CTC grade II;

11. Hormonal treatment (prior hormonal treatment allowed).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2000
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	05-08-2009
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	NL1834
NTR-old	NTR1944
Other	METC UMCG 2000/132 : METC AMC 2000/167
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A