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

Gepubliceerd: 05-08-2009 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21712

Bron
NTR

Verkorte titel
TAX 613

Aandoening

Metastatic or advanced breast cancer, second line chemotherapy

Ondersteuning

Primaire sponsor: Sanofi-Aventis
Overige ondersteuning: Sanofi-Aventis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. PFS;
2. TTF.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

> 50% participants deceased.

Onderzoeksproduct en/of interventie

Two different regimens.

Contactpersonen

Publiek

AMC
Dept Medical Oncology
A.M. Westermann
Meibergdreef

Amsterdam
The Netherlands
0031 (0)20 5669111

Wetenschappelijk

AMC
Dept Medical Oncology
A.M. Westermann
Meibergdreef

Amsterdam
The Netherlands
0031 (0)20 5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-07-2000
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1834
NTR-old	NTR1944
Ander register	METC UMCG 2000/132 : METC AMC 2000/167
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A