Activiteit van trastuzumab toevoeging aan chemotherapie in patienten met gemetastaseerd HER2 negatief borstkanker en HER2 positieve circulerende tumorcellen

Gepubliceerd: 24-03-2015 Laatst bijgewerkt: 15-05-2024

We hypothesize that patients with a HER2-negative primary tumor but with at least one HER2-positive CTC benefit from HER2 targeted treatment with trastuzumab

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Borstaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20549

Bron
Nationaal Trial Register

Verkorte titel
CareMore-Trastuzumab

Aandoening

- Borstaandoeningen

Aandoening

Breast cancer, borstkanker, HER2, ER, PIK3CA, CTC, circulating tumor cell, circulerende tumorcellen, metastasen, metastasis, trastuzumab, herceptin, docetaxel

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Erasmus MC Cancer Institute, department of Medical Oncology
Overige ondersteuning: EU-FP7, CareMore, project number 601760-2

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Determine if metastatic breast cancer patients with HER2-negative primary tumors but HER2-positive CTCs benefit from trastuzumab-containing chemotherapy

Toelichting onderzoek

Achtergrond van het onderzoek

Today’s treatment of metastatic breast cancer is guided by characteristics of the primary tumor, while 90% of deaths due to breast cancer occur as a consequence of etastases. It is appreciated that tumor characteristics may differ between the primary tumor and the metastases. In addition, evidence is accumulating that there are patients with HER2-negative primary tumors who respond to trastuzumab-based chemotherapy. One group of patients with HER2-negative primary tumors who might benefit from trastuzumab-based approaches is patients with HER2-positive circulating tumor cells (CTCs). CTCs are cancer cells present in the peripheral blood of patients with metastatic breast cancer and are thought to represent characteristics of the metastases. We hypothesize that patients with a HER2-negative primary tumor but with at least one HER2-positive CTC benefit from HER2 targeted treatment with trastuzumab.

Doel van het onderzoek

We hypothesize that patients with a HER2-negative primary tumor but with at least one HER2-positive CTC benefit from HER2 targeted treatment with trastuzumab

Onderzoeksopzet

- Screening

- Inclusion

- 6 months respons evalution

Onderzoeksproduct en/of interventie

Screening:

Blood collection for CTC enumeration and HER2 staining.

Study (only woman with HER2-positive CTCs are included):

- LVEF mesurement

- Blood collection for CTC isolation and in situ characterization (ER, pHER2 & PIK3CA)

- Administration of trastzumab/docetaxel in patients with at least one HER2+ CTC

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder

65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female patient with metastatic breast cancer with HER2-negative primary tumor

- Age > 18 years old

- WHO performance status < 2

- Considered fit enough to receive trastuzumab/docetaxel by the treating physician

- Able to understand and give written informed consent

- Female patient with metastatic breast cancer with HER2-negative primary tumors with the presence of at least one HER2-positive CTC

- Adequate left-ventricular ejection fraction (LVEF) of at least 45%

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous chemotherapy for metastatic disease.

- Adjuvant chemotherapy within 6 months prior to treatment start.

- Hormonal antitumor treatment within one week prior to treatment start.

- Symptomatic CNS metastases (the presence of at least one key symptom in combination with radiologic evidence (positive contrast-enhanced CT or MRI of the brain))

Onderzoeksopzet

Opzet

Fase onderzoek:	2
Type:	Interventie onderzoek
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	Historische controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-03-2015
Aantal proefpersonen:	18
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	18-02-2015
Soort:	Eerste indiening
Toetsingscommissie:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46900
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4977
NTR-old	NTR5115
CCMO	NL51298.078.14
OMON	NL-OMON46900

Resultaten