The effect of anti-HER2 therapy in metastatic breast cancer wih HER2-negative primary tumor but HER2-positive circulating tumor cells

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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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast disorders
Study type	Interventional

Summary

ID

NL-OMON20549

Source
Nationaal Trial Register

Brief title
CareMore-Trastuzumab

Condition

- Breast disorders

Health condition

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

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute, department of Medical Oncology
Source(s) of monetary or material Support: EU-FP7, CareMore, project number 601760-2

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Impact of pHER2 and PIK3CA mutations in CTCs on the outcome to trastuzumab based chemotherapy

- PIK3CA mutation status, pHER2 and ER expression status on primary tumor tissue to compare with CTCs

- CTCs enumerated and isolated by CellSearch to CTCs enumerated and characterized by CytoTrack

- Whether the percentage of HER2-positive CTCs is associated with outcome on trastuzumab/docetaxel

Study description

Background summary

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.

Study objective

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

Study design

- Screening

- Inclusion

- 6 months respons evalution

Intervention

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

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- 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%

Exclusion criteria

- 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))

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Historical
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2015
Enrollment:	18
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	18-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 46900

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results