

Prognostic value of HER2-positive circulating tumor cells in metastatic breast cancer patients treated with aromatase inhibitors

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We hypothesize that patients with a primary tumor expressing ER and lacking HER2 but with CTCs expressing HER2 have a worse response on hormonal therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast disorders
Study type	Observational non invasive

Summary

ID

NL-OMON24808

Source

NTR

Brief title

CareMore-AI study

Condition

- Breast disorders

Health condition

Breast cancer, borstkanker, HER2, ER, PIK3CA, CTC, circulating tumor cell, circulerende tumorcellen, metastasen, metastasis, AI, aromatase inhibitor, letrozole, anastrozole, arimidex, aromataseremmer

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, projectnumber 601760-2

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

To determine the impact of HER2 expression in CTCs taken at baseline on outcome to AIs in metastatic breast cancer patients with an ER-positive primary tumor

Secondary outcome

- To determine impact of PIK3CA mutation status, pHER2 and ER expression status in CTCs taken at baseline on outcome to AIs
- To determine the PIK3CA mutation status, pHER2 and ER expression status on primary tumor tissue to compare with CTCs
- To compare CTCs enumerated and isolated by CellSearch to CTCs enumerated and characterized by CytoTrack
- To explore whether the percentage of HER2-positive CTCs is associated with outcome on AIs

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 metastases. Treatment of metastatic breast cancer patients with hormonal agents is often employed in the clinic. A worse outcome to hormonal therapy was observed in patients with primary tumors expressing both ER and HER2 compared to patients with primary tumors positive for ER but negative for HER2. Metastatic breast cancer patients are still treated based on primary tumor characteristics, while it is now increasingly appreciated that important characteristics like ER and HER2 expression may differ between the primary tumor and the

metastatic lesion. Circulating tumor cells (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 HER2 status on CTCs will be stronger associated with outcome to hormonal therapy than HER2 status in primary tumors. If so, this means that patients with primary tumors expressing ER and lacking HER2, but with CTCs expressing HER2, should not be treated with hormonal agents.

Study objective

We hypothesize that patients with a primary tumor expressing ER and lacking HER2 but with CTCs expressing HER2 have a worse response on hormonal therapy.

Study design

- Baseline
- 6 months evaluation

Intervention

Blood draw for CTC enumeration and characterization (80 mL of blood) at baseline

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
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
- Age \geq 18 years
- Written informed consent

Exclusion criteria

- Adjuvant chemotherapy within 6 months prior to treatment start
- Other anticancer chemotherapy, use of biological response modifiers, or immunotherapy within two weeks prior to treatment start. Hormonal antitumor treatment within one week prior to treatment start.
- Serious illness or medical unstable condition prohibiting adequate treatment and follow-up

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Other

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: 10-02-2015
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: 47479
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4884
NTR-old	NTR5121
CCMO	NL50622.078.14
OMON	NL-OMON47479

Study results