CareMore study 1: prognostic value of HER2-positive circulating tumor cells in metastatic breast cancer patients treated with aromatase inhibitors (CareMore-AI study)

Published: 10-02-2015
Last updated: 15-05-2024

The primary objective is 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 objectives are to determine impact of HER2 expression...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON47479

Source
ToetsingOnline

Brief title
CareMore-AI

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Metastatic breast cancer, metastatic mammary cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: EU-FP7

Intervention

Keyword: Aromatase inhibitor, Circulating tumor cells, Metastatic breast cancer, Molecular characterization

Outcome measures

Primary outcome

The primary endpoint for this study will be the 6 months PFR in patients who

had HER2-positive CTC*s at the start of AI treatment (group 1)

Secondary outcome

Secondary objectives are to determine impact of HER2 expression in CTCs taken

at baseline on outcome to AIs combined with CDK4/6 inhibitors (group 1) In

addition, we will investigate genomic heterogeneity within a patient on single

CTC level (group 1, 2, 3)

Study description

Background summary

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

The primary objective is 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 objectives are to determine impact of HER2 expression in CTCs taken at baseline on outcome to AIs combined with CDK4/6 inhibitors. In addition, we will investigate genomic heterogeneity within a patient on single CTC level.

Study design

Patients with metastatic breast cancer, with a HER2-negative and ER-positive primary tumor and who are candidate to receive first-line aromatase inhibitor treatment, will be included in this prospective, open study. In all patients, 50 mL of blood will be drawn at baseline for CTC CellSearch enumeration and CTC characterization (as described in chapter 8.3). Following the start of AI treatment, patient progression will be monitored for 6 months.

Based on the patients* CTC count and the emergence of HER2-positive CTCs (as evaluated with the CellSearch method, see chapter 8.3.1), patients can be divided into three groups:
1. CTC*s detectable, of which a subset is HER2-positive
2. CTC*s detectable, of which all are HER2-negative
3. No CTC*s detectable

When 6 months have passed since the inclusion of the last patient and the data have been validated, the final analysis will be performed.

Study burden and risks

In all patients, 50 mL blood for CTC enumeration and CTC characterization will be drawn at baseline during another blood draw that is already required for standard care. Therefore, no risks are associated with participation in this study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Female patient with metastatic breast cancer
- Age >= 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 type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2015
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	10-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-12-2019
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24808
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50622.078.14
OMON	NL-OMON24808