HER2-PET as a diagnostic tool in breast cancer patients with a clinical dilemma

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

Summary

ID

NL-OMON39796

Source
ToetsingOnline

Brief title
Clinical value of 89Zr-trastuzumab

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting A Sister□s Hope

Intervention

Keyword: clinical dilemma, CTC, HER2-PET, metastatic breast cancer

Outcome measures

Primary outcome

Concordance between HER2-PET results and anti-HER2 therapy is defined as HER2 positive lesion(s) on HER2-PET and subsequent anti-HER2 therapy; or no HER2 positive lesions on HER2-PET and no subsequent anti-HER2 therapy. It is considered a clinically relevant contribution of HER2-PET to anti-HER2-therapy decisions if there is a concordance in at least 2/3 of included patients.

Secondary outcome

Secondary endpoints are

• Correlation of HER2-PET results and questionnaire results regarding clinical value of HER2-PET for the referring clinician

• Correlation of HER2-PET results with standard conventional work-up

• Correlation of HER2-PET results and HER-2 expression by CTCs.

Study description

Background summary

Information about the presence of human epidermal growth factor receptor 2 (HER2) in tumor lesions in breast cancer patients is essential for diagnostic and therapeutic management of metastatic breast cancer. In daily practice however, obtaining a metastasis biopsy can be difficult or impracticable. Therefore, clinicians can be faced with a persistent clinical dilemma in some breast cancer patients, leading to suboptimal therapy decisions due to lack of HER2 receptor information. Circulating tumor cells (CTCs), which may provide additional information, have so far not been able to replace the biopsy. To solve this problem, non-invasive whole body visualization and quantification of

HER2 expression by means of the HER2-PET may be a valuable tool.

Study objective

The primary objective is to assess the contribution of HER2-PET to subsequent anti-HER2-therapy decisions. Secondary objectives are assessment of clinical value of HER2-PET for the referring clinician; correlation of HER2-PET with standard conventional work-up and HER-2 expression by CTCs.

Study design

In this prospective imaging study, eligible patients will receive one HER2-PET and CTC analysis in addition to standard work up for metastatic disease. Subsequent administration of anti-HER2 therapy will be evaluated. Referring physicians fill in three questionnaires, one before HER2-PET and two after HER2-PET. Blood sampling for CTC analysis will be drawn ahead of tracer injection 4 days before the HER2-PET.

Intervention

Injection with the tracer 89Zr-trastuzumab and 89Zr-trastuzumab PET/CT four days post injection.

Study burden and risks

For this study the patients will make in total 4 extra visits to the clinic. After screening procedure is accomplished, patients will visit for blood sampling (CTC analysis) and tracer injection, followed by the HER2-PET 4 days later. Finally a result visit will take place. The HER2-PET implements a radiation burden of 19.5 mSV. Furthermore, patients may experience side effects of the tracer. Until now just once a side effect in terms of a hypersensitivity reaction has been observed. Appropriate precautions have been taken to reduce the risk of such an event. Potential benefit for the patients in this study comes from the potential additional knowledge regarding HER2 receptor status of the metastatic disease by means of the HER2-PET, and guiding of anti-HER2 therapy based on this PET. Also, this study will provide data that may improve patient care in the future for other patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with a history of histological and/or cytological proven HER2-positive primary breast cancer. HER2-positivity is defined as:
a) HER2 immunohistochemical score of 3+, or
b) HER2 immunohistochemical score of 2+ and positive FISH for HER2/c-erbB2 amplification.
2. Patients with suspected metastatic disease or local recurrence of HER2-positive breast cancer and a clinical dilemma:
a) in whom standard work up with imaging has failed to solve the clinical dilemma (diagnostic/therapeutic), leaving issues with regard to HER2 status of lesions and
b) in whom a biopsy is desirable but cannot (easily) be performed due to technical or patient factors or otherwise.
3. Standard work-up with imaging is defined as CT chest and abdomen, bone scintigraphy, as well as FDG-PET.
4. Age >18 years of age.
5. WHO performance status 0-2.

Exclusion criteria

1. Pregnant or lactating women.

2. Prior allergic reaction to immunoglobulins or immunoglobulin allergy.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	05-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-003789-41-NL
ClinicalTrials.gov	NCT01832051
CCMO	NL41707.042.12