HER Image: 89Zr-DFO* trastuzumab PET in patients with breast cancer - a pilot study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON55969

Source
ToetsingOnline

Brief title
HER Image

Condition

- Metastases

Synonym
Mammary carcinoma; breast cancer.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Astra Zeneca

Intervention

Keyword: Breast cancer, HER2, PET

Outcome measures

Primary outcome

- Biodistribution: 89Zr-DFO*-trastuzumab uptake (standard uptake values (SUVmean, %ID/kg) in normal organs/tissues and bloodpool.

- Biodistribution as above from historical controls with HER2+ breast cancer (n = 20) who underwent 89Zr-trastuzumab PET imaging.

Secondary outcome

- Tumor uptake: 89Zr-DFO*-trastuzumab uptake (SUV, %ID/kg) in tumor lesions.

- Tumor uptake as above in historical controls with HER2+ breast cancer (n = 20) who underwent 89Zr-trastuzumab PET imaging.

- Whole blood and plasma PK of 89Zr-DFO*-trastuzumab

- Image-derived PK for 89Zr-DFO*-trastuzumab

- Literature-derived PK for unlabelled trastuzumab

- Visual PET imaging analysis of tumor uptake of 89Zr-DFO*-trastuzumab and 89Zr-trastuzumab.

- Tumor-to-blood ratio of 89Zr-DFO*-trastuzumab (whole blood and plasma as well as image derived)

- Tumor-to-image derived blood uptake ratio of 89Zr-trastuzumab

- HER2 expression measured by IHC on tumor biopsies

Study description

Background summary

Different forms of breast cancer are known. On the surface, the cancer cells can have different properties (receptors), which promote the growth of these cells. In 20% of these tumors, the "human epidermal growth factor receptor 2" (HER2) is found on the surface of the cells. Nowadays, there are many drugs available to block this growth. In case of a HER2 positive tumor, trastuzumab (Herceptin®) is often prescribed, sometimes in combination with chemotherapy. This is mostly not the case with HER2-low.

In order to choose the right treatment for the patient, it is therefore of great importance to know whether HER2 is present on the cancer cells. Over time, however, HER2 may disappear or emerge. This makes it even more important to have up-to-date information about the presence of HER2 in the metastases. In this way, it can be prevented that patients receive too much or too little treatment.

To find out whether metastases have HER2, tissue biopsy of a metastasis must be done. Despite the fact that the biopsy provides important information, only one metastasis is investigated. But not all metastases need to have the same properties. That is why we do research on scans that show all places in the body where HER2 is present. By using the detection agent for HER2 (= radioactive trastuzumab, or [89Zr]-DFO*trastuzumab) at different times after administration, we can better understand how radioactive trastuzumab binds to HER2. In this way we hope to obtain additional information about the presence of HER2 from all metastases.

Study objective

The aim of this study is to investigate in patients with metastatic HER2 positive or HER2-low breast cancer whether a PET scan with a new HER2 tracer ([89Zr] DFO*trastuzumab) accurately depicts all abnormalities and whether ultimately this HER2 PET scan can be used to predict response to treatment.

Study design

During the 1st visit, radioactive trastuzumab will be administered. For administration, 2 infusion needles are inserted - one into each arm. Blood will be taken via one IV while the other IV is used to administer the radioactive trastuzumab into the bloodstream. In a period of 2 hours after administration, 4 vials of blood will be taken. In the first three patients, a PET scan will be made 1 hour after administration.
The 2nd visit follows 1 day later where a PET scan is made and 1 vial of blood is taken
The 3rd visit follows 4 days after the administration of radioactive

trastuzumab in which a PET scan is made and 1 vial of blood is taken
The 4th visit follows 6 days after the administration of radioactive trastuzumab in which a PET scan is made and 1 vial of blood is taken

Intervention

Biopsy of the primary tumour or a metastasis to confirm HER-status. Applicible only if the most recent biopsy is more than 16 weeks old, or if in that timeframe a therapy switch occured.

Study burden and risks

The study requires 4 additional hospital visits. 2 IVs are placed and blood samples will be taken at 7 different timepoints (of which 3x by means of an extra venipuncture). It is possible that people may experience local pain complaints. The scans are made after the injection of radioactive trastuzumab. For the (three or four) scans, patients must lie supine for 60 minutes each time. We use radioactive materials and X-rays for the scans. The total additional radiation exposure in this study is a maximum of 24 mSv.

A biopsy may be uncomfortable. Risks associated are bleeding, infection, pain and neurological damage.

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

Patients with:
- HER2+ or HER2-low breast cancer with metastatic disease,
- and starting systemic therapy or having stable, RECIST measurable disease (with or without treatment).

• A recent (< 16 weeks of start of study) biopsy confirming HER2-status, as long as no therapy changes took place within those 16 weeks.
• Able to undergo PET imaging procedures.
• At least one lesion of at least 1.5 cm amenable for PET imaging
• Age >18 years of age, willing and able to comply with the protocol as judged by the investigator.
• Signed written informed consent.
• Have a World Health Organisation (WHO) performance status of 0-2.
• Life expectancy of > 3 months.
• Have measurable disease based on RECIST 1.1.
• Adequate organ and bone marrow function, as deemed acceptable by the treating physician

Exclusion criteria

• Contraindications for systemic treatment (as will be assigned by treating physician).
• Pregnant or lactating women.
• Prior allergic reaction to immunoglobulins or immunoglobulin allergy.
• Inability to comply with study procedures.
• Has substance abuse or any other medical conditions such as clinically significant cardiac or psychological conditions, that may, in the opinion of the investigator, interfere with the subject*s participation in the clinical study or evaluation of the clinical study results.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-06-2023
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	89Zr-DFO* trastuzumab
Generic name:	89Zr-DFO* trastuzumab

Ethics review

Approved WMO Date:	06-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2024
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	EUCTR2022-003120-40-NL
ClinicalTrials.gov	NCT05955833
CCMO	NL82608.018.22