Can 89Zr-atezolizumab PET scan identify patients with metastatic invasive lobular breast cancer who will respond to chemotherapy-immune checkpoint inhibition?

Published: 11-04-2019
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Primary objective: To evaluate the feasibility to detect a change in tumor PD-L1 expression on a 89Zr-atezolizumab PET scan, before and after two carboplatin induction treatments.

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

Summary

ID

NL-OMON47947

Source
ToetsingOnline

Brief title
ImaGelato study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
lobular breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: grant van het UMCG Kanker Research Fonds

Intervention

Keyword: 89Zr-atezolizumab PET scan, Lobular breast cancer

Outcome measures

Primary outcome

Change in tumor uptake between 89Zr-atezolizumab PET scan at baseline and after two carboplatin induction treatments, defined as decline or increase of standardized uptake value (SUV) of 30% or more, described as per lesion and per patient.

Secondary outcome

* Relation of 89Zr-atezolizumab tumor uptake (at baseline, after carboplatin induction, and change between the two scans) per lesion and per patient with response to carboplatin-atezolizumab per lesion and per patient.

* Relation of 89Zr-atezolizumab tumor uptake at baseline and after carboplatin induction, with tumor biopsy assessments (PD-L1 IHC, mRNA and other potential markers of interest in the setting of immune response such as macrophages).

Study description

Background summary

Recent studies show that an 89Zr-atezolizumab PET scan can predict the sensitivity to an immune therapy treatment with atezolimab. But if the scan can also show possible changes in chemotherapy sensitivity, is not known. The use of the 89Zr-atezolizumab is experimental and not-approved for standard tumor imaging. Therefore we would like to perform this special PET scan in the

ImaGelato study, in patients participating in the GELATO study in the UMCG, prior and during chemotherapy.

Study objective

Primary objective: To evaluate the feasibility to detect a change in tumor PD-L1 expression on a 89Zr-atezolizumab PET scan, before and after two carboplatin induction treatments.

Study design

This exploratory single center feasibility ImaGelato study is conducted as an imaging side study to the Dutch GELATO trial (ClinicalTrials.gov NCT03147040; METc 2018/113).

Intervention

All patients will undergo two 89Zr-atezolizumab PET scans, one at baseline and one after two doses carboplatin induction treatment. The PET scan will be performed 4 days after tracer injection.

Study burden and risks

For the ImaGelato study, 3 extra visits to the clinic are required in addition to those for the GELATO trial: (1) for screening plus injection (2) for the first PET scan, (3) for the second tracer injection OR second PET scan. The other study visits will be performed simultaneously with visits for the GELATO trial. The PET scan will induce an extra radiation burden of about 18 mSv, and 1.5 mSv per low-dose CT scan (in total 39 mSv for 2 PET scans). No individual benefit is expected from study participation. In the future, this study may potentially contribute to improved insight in the effect of chemotherapy on response to immune checkpoint inhibitors in cancer types that are relatively unresponsive to immunotherapy such as (lobular) breast cancer. Ultimately this study may contribute to optimal patient selection and treatment with immunotherapy. This is of relevance in view of optimal treatment for individual patients, avoiding unnecessary toxicity and financial burden.

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. A patient must meet the inclusion criteria of the GELATO trial (see in attachment the protocol)
2. Able to give written informed consent and to comply with the ImaGelato protocol

Exclusion criteria

1. Contra-indication for 89Zr-atezolizumab PET scan
2. Any approved anti-cancer therapy, including chemotherapy or hormonal therapy within *14 days prior to the first 89Zr-atezolizumab injection. Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days prior to the first 89Zr-atezolizumab injection.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-atezolizumab
Generic name:	Tracer 89Zr-atezolizumab

Ethics review

Approved WMO Date:	11-04-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-07-2019
Application type:	First submission
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	EUCTR201900180-NL
CCMO	NL69601.042.19
Other	volgt