Androgen receptor and estrogen receptor imaging in metastatic breast cancer patients

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The aim of this study is to evaluate androgen receptor (AR) and estrogen receptor (ER) expression non-invasively by means of PET imaging with the tracers 18F-FDHT and 18F-FES. To verify the PET results, the standard diagnostic biopsy will be...

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

Summary

ID

NL-OMON39731

Source
ToetsingOnline

Brief title
AR imaging metastatic breast cancer

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Center for Translational Molecular Medicine (CTMM)

Intervention

Keyword: androgen receptor, estrogen receptor, imaging, PET

Outcome measures

Primary outcome

The sensitivity and specificity of FDHT PET and FES PET to visualize and quantify AR- and ER-expression respectively, when compared to imunnohistochemistry on the biopsied metastasis.

Secondary outcome

- the heterogeneity of FDHT and FES uptake among metastases within an individual patient, as well as the inter-patient differences.

- interobserver variation in PET interpretation between two independent observers from both study sites (VUMC and UMCG)

Study description

Background summary

Patients with breast cancer can nowadays be treated with endocrine therapy when the tumor is sensitive to estrogens (which is in case of estrogen receptor [ER] positive disease. It is known that tumor ER status can change during disease progression and up to 30% of the metastases show discordant ER-expression compared to the primary tumor. For this reason, several guidelines now recommand to perform a biopsy of a metastasis to re-evaluate ER status (among others). It is however not always possible to perform a biopsy due to patient factors or the location of the lesion. Moreover, a biopsy only provides information of a single lesion and may not always be representative for the overall ER status of the patient's disease. For this reason, it would be valuable to obtain information about tumor endocrine sensitivity by non-invasive measurements like positron emission tomography (PET) imaging.

Study objective

The aim of this study is to evaluate androgen receptor (AR) and estrogen

receptor (ER) expression non-invasively by means of PET imaging with the tracers 18F-FDHT and 18F-FES. To verify the PET results, the standard diagnostic biopsy will be performed as well as a CT-scan and bone scan.

Study design

Patients will undergo two experimental procedures: the FES-PET scan to image ER-expresion; and the FDHT-PET scan to image AR-expression.

Within a 6-8 week timeframe other (standard) diagnostics will also be performed (CT-scan, bone scan and tumor biopsy).

Intervention

PET scan (twice)

Study burden and risks

The radiation burden for the patient is ~11 mSv

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. Metastatic breast cancer, with at least one known metastasis outside of the liver
2. Presence of a lesion that is safely accessible for tumor biopsy (may be liver lesion)
3. Postmenopausal status defined as one of the following:
a. age >=60 years
b. previous bilateral oophorectomy
c. age <60 years and amenorrhea for >12 months in the absence of interfering hormonal therapies (such as LH-RH agonists and ER-antagonists)
d. patients age <60 years using an ER-antagonist should have amenorrhea for > 12 months and FSH >24 U/L and LH >14 U/L
e. patient age <60 years using LH-RH agonists should continue LH-RH-agonists until after the PET procedures
4. Initially ER-positive tumor histology.
5. ECOG performance status 0-2.
6. Signed written informed consent
7. Able to comply with the protocol

Exclusion criteria

1. Use of estrogen receptor ligands, including tamoxifen, fulvestrant or estrogens, or androgen receptor ligands, during the 6 weeks before entry into the study
2. Life-expectancy <= 3 months

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):	16-09-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-FDHT
Generic name:	16beta-[18F]fluoro-5alpha-dihydrotestosterone
Product type:	Medicine
Brand name:	18F-FES
Generic name:	16alpha-[18F]fluoro-17beta-estradiol

Ethics review

Approved WMO Date:	13-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-10-2014
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	EUCTR2012-003981-42-NL
CCMO	NL41954.042.12