In vivo imaging of the effect of fulvestrant on availability of estrogen receptor binding sites in metastatic breast tumor lesions using [18F]FES-PET

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The aim of this study is to quantify residual ER binding sites during fulvestrant therapy, compared to the tracer uptake prior to fulvestrant therapy.

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

Summary

ID

NL-OMON39073

Source
ToetsingOnline

Brief title
ER imaging to evaluate fulvestrant pharmacodynamics

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
metastatic 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,Astra

Zeneca,Educational Grant vanuit farmaceutische industrie

Intervention

Keyword: Breast Cancer, Estrogen Receptor, FES-PET, Fulvestrant

Outcome measures

Primary outcome

Absolute and relative changes in tracer uptake values during fulvestrant therapy (after 1 month and 3 months) compared to tracer uptake prior to fulvestrant therapy.

Secondary outcome

Correlation between tumor response and absolute and relative changes in tracer uptake

Study description

Background summary

Estrogen receptor (ER) positive metastatic breast cancer patients are often treated with antihormonal therapy. Fulvestrant is an ER-antagonist that irrversibly blocks the ER and downregulates its expression level. A dose-response has been shown for fulvestrant's effects on the ER, whereby the current dose does not yet fully downregulate ER expression. Given the fact that the current standard dose is generally well tolerated, dose-escalation may be possible in the near future. Ideally, a biomarker should be available to evaluate the effects of fulvestrant on the ER to select patients that may benefit from dose-escalation or increasing the dose frequency. The standard test to evaluate the ER expression is by immunohistochemistry which can be performed on biopsies tissue. However, it is not always easy to obtain a biopsy due to accessibility or risks for complications and furthermore a biopsy only gives information about a single lesion and may not be representative for the ER expression in other metastases.
Molecular imaging of the ER with radioactive labeled estrogen (FES) can be used to quantify ER expression. The aim of this study is to quantify residual ER binding sites during fulvestrant therapy, compared to the tracer uptake prior to fulvestrant therapy. Imaging of ER binding sites may be used to optimize

individual patient dosing in the future.

Study objective

The aim of this study is to quantify residual ER binding sites during fulvestrant therapy, compared to the tracer uptake prior to fulvestrant therapy.

Study design

In this study we will observe the influence of fulvestrant (a commonly used estrogen receptor antagonist) on the uptake of radioactive-labeled estradiol by estrogen receptor positive tumors. Tracer uptake will be evaluated prior to the start with antihormonal therapy, and during antihormonal therapy.

Study burden and risks

The radiation burden will be approximately 13.2 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. Patients with a history of histological proven ER-positive primary breast cancer and, whenever available, histological proven ER-positive recurrence.
2. Post-menopausal status (age >= 45 years with amenorrhea for > 12 months [with or without concomitant use of LHRH-/GNRH-agonists]or prior bilateral ovariectomy
3. Documentation of a negative pregnancy test must be available for women less than 2 years after menopause
4. Progressive disease after 2 lines of hormonal therapy
5. No previous fulvestrant treatment
6. ER-antagonists should be discontinued for 5 weeks prior to FES-PET to prevent false negative FES_PET results, the use of aromatase inhibitors prior to FES-PET is allowed.
7. At least one measurable lesion according to RECIST v1.1 that is localized outside of the liver
8. ECOG performance status 0, 1 or 2
9. Life expectancy > 3 months
10. Creatinine clearance >= 30 ml/min
11. Age >= 18 years
12. Signed written informed consent
13. Able to comply with the protocol

Exclusion criteria

1. Evidence of central nervous system metastases
2. Presence of life-threatening visceral metastases
3. > 3 lines of endocrine therapy for metastatic disease
4. > 2 lines of chemotherapy in metastatic disease

Study design

Design

Study phase:	2
Study type:	Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-FES
Generic name:	16-alpha-[18F]-fluoro-17-bèta-estradiol
Product type:	Medicine
Brand name:	Faslodex
Generic name:	Fulvestrant
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	16-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	24-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	05-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	07-03-2013
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	EUCTR2010-023987-41-NL
ClinicalTrials.gov	NCT01377324
CCMO	NL34770.042.10

Study results

Date completed:	26-08-2013
Actual enrolment:	16