In vivo imaging of ER density to guide and improve tailored therapy for acquired anti-hormonal resistant breast cancer

Published: 10-03-2009
Last updated: 11-05-2024

To discriminate the acquired anti-hormonal resistance phenotypes in patients based on ER expression levels by FES-PET in order to select patients eligible for estrogen 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-OMON38021

Source
ToetsingOnline

Brief title
In vivo imaging of the ER receptor

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, ER receptor, Imaging, In vivo

Outcome measures

Primary outcome

Clinical/biochemical/radiological response on Estradiol versus ER expression

on FES-PET signal preferable with an ER expressions density measured on recent

taken tumor tissue

Secondary outcome

Physical burden of FES-PET

Study description

Background summary

Title: Imaging of ER density to guide and improve tailored therapy for acquired anti-hormonal resistant breast cancer

Breast cancer is the most frequent tumor among women in the Netherlands. In metastatic disease standard systemic treatment options are hormonal therapy and chemotherapy. Hormonal treatment is effective for breast tumors with a hormone receptor positive breast cancer. The interference in the estrogen signaling pathway with tamoxifen, aromatase inhibitors or faslodex is an important intervention modality with relatively mild side effects. However, eventually this therapy becomes ineffective, as all patients will acquire hormonal resistance. For metastatic estrogen receptor (ER) positive breast cancer, interference in the estrogen signaling pathway with tamoxifen, aromatase inhibitors or faslodex is an important intervention modality with relatively mild side effects. However, eventually this therapy becomes ineffective, as all patients will acquire resistance. Three types of resistance can be identified in-vitro: resistance in which ER expression is negative (ER-; mainly epigenetically silenced; 20% of patients), resistance in which ER expression is preserved and tumors still require estrogen for their growth (ER+; 50% of patients) and resistance , in which ER expression is increased and tumors are hypersensitive to estrogens (ER++; 30% of patients). Early identification of the resistance phenotypes (ER expression levels) could govern optimal treatment

decision-making, as most likely ER+ and ER++ phenotypes will benefit best form additional anti-hormonal therapy and estrogen treatment, respectively, whereas chemotherapy remains for ER-.

Study objective

To discriminate the acquired anti-hormonal resistance phenotypes in patients based on ER expression levels by FES-PET in order to select patients eligible for estrogen therapy.

Study design

Observational study

Study burden and risks

Extra stralingsbelasting van 4.4 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. Acquired antihormonal resistant advanced breast cancer showing progression after two or more lines of antihormonal treatment.
2. Treatment with estradiol.
3. Age >= 18 years
4. ECOG performance status 0-2
5. Signed written informed consent
6. Able to comply with the protocol

Exclusion criteria

1. Life-expectancy <= 3 months
2. Uncontrolled CNS metastases
3. Uncontrolled hypercalcemia
4. Treatment with any investigational drug within 30 days before start of study
5. Pregnant or lactating women. Documentation of a negative pregnancy test must be available for pre-menopausal women with intact reproductive organs and for women less than two years after menopause
6. Women of childbearing potential unless (1) surgically sterile or (2) using adequate measures of contraception
7. One of the relative contra-indications underneath, unless estradiol is the only available treatment option available:
a. Serious uncontrolled concurrent illness, e.g. autoimmune disorders
b. New York Heart Association (NYHA) class III/IV congestive heart failure
c. Dyspnea at rest due to any cause
d. Diabetes mellitus
e. History of thrombosis

Study design

Design

Study phase: 2

Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2013
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	EUCTR2008-002657-20-NL
CCMO	NL23268.042.08