Moleculaire beeldvorming van de oestrogeenreceptor dichtheid om de hormonale behandelingsmogelijkheden voor patiënten met borstkanker te verbeteren.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26431

Source
Nationaal Trial Register

Health condition

breast cancer acquired anti-hormonal resistance

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG), department of medical oncology
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

With a ROC analysis we will determine the optimal sensitivity and specificity of FES-PET in

relation with the standard uptake value (SUV) to predict response to estrogen therapy.

Secondary outcome

1) To discriminate the acquired anti-hormonal resistant phenotypes in patients based on ER expression levels by FES-PET;

2) Correlation between SUV and response to therapy.

Study description

Background summary

Patients with different types of acquired anti-hormonal resistance are likely to respond differently to a particular kind of treatment. The ER+ subtype would most likely initially respond to a second or third line of anti-hormonal therapy, but ultimately these tumors will again become resistant. At that stage, chemotherapy is the only treatment available. Chemotherapy is currently also the only treatment option for tumors of the ER- phenotype. In contrast, treatment with estrogen is highly effective for the hypersensitive ER++ phenotype and could therefore be an attractive alternative for chemotherapy in this selected group of patients. Currently, this treatment option is not utilized due to the absence of proper stratification methods.
FES-PET may allow identification of patients without ER expression (ER-), patients with preserved ER expression (ER+) and patients with ER overexpression (ER++). This project therefore aims to investigate in a pilot clinical study whether the acquired anti-hormonal resistant phenotypes in breast cancer patients can be discriminated on basis of ER expression levels as measured by FES-PET. The discrimination of phenotypes could allow selection of patients eligible to estrogen treatment.

Study objective

Measuring ER-density with FES-PET can be used as a predictive test to select patients sensitive for estrogen therapy.

Study design

At the start of study ER densitity will be determined by FES-PET, the patient will be staged with CT-scan, and baseline clinical information will be collected (laboratory results, VAS-score, ECOG performance, ECG).

Follow-up will take place monthly during the first 3 months, and thereafter every 3 months.

Intervention

In patients with acquired antihormonal resistance, eligible for estrogen therapy, a FES-PET scan will be made to determine FES-PET tumor uptake (which corresponds to estrogen receptor expression levels). Immediately after the FES-PET scan, all patients will start with a standard accepted dose of 2mg estradiol TID. Therapy response will be monitored by regular follow-up. RECIST criteria and clinical benifit will be used as criteria. In case of disease progression before end of the study period, estradiol treatment will be stopped.

Contacts

Public
Dept. of Medical Oncology
University Medical Center Groningen
PO Box 30.001
G.A.P. Hospers
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161
Scientific
Dept. of Medical Oncology
University Medical Center Groningen
PO Box 30.001
G.A.P. Hospers
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161

Eligibility criteria

Inclusion criteria

1. Patients with the diagnosis of acquired anti-hormonal resistant advanced breast cancer showing progression after two or more lines of antihormonal treatment;

2. Treatment with estradiol will be started;

3. Age> 18 years;

4. ECOG performance status 0-2.

Exclusion criteria

1. Life Expectancy <3 months;

2. Uncontrolled CNS metastases;

3. History of thrombosis;

4. Uncontrolled hypercalcemia;

5. Treatment with any investigational drug within 30 days before start of study;

6. Serious uncontrolled concurrent illness, e.g. autoimmune disorders;

7. New York Hearth Association (NYHA) class III/IV congestive heart failure;

8. Dyspnea at rest due to any cause;

9. 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;

10. Women of childbearing potential unless a) surgically sterile or b) using adequate measures of contraception.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010

Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion Date:	01-03-2010
Application type:	First submission

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
NTR-new	NL2117
NTR-old	NTR2234
Other	METc UMCG : 2008.277
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Dehdashti F, Mortimer JE, Trinkaus K. et al. PET-based estradiol challenge as a predictive biomarker of response to endocrine therapy in women with estrogen-receptor-positive breast cancer. Breast Cancer Res Treat (2009) 113:509-517;
2. Ellis MJ, Dehdashti F, Kommareddy A et al. A randomized phase 2 trial of low dose (mg daily) versus high dose (30mg daily) estradiol for patients with estrogen receptor positive aromatase inhibitor resistant advanced breast cancer. Breast Cancer Symposium 2008 San

Antonio.