VEGF imaging for early breast cancer detection.

Published: 05-10-2009
Last updated: 04-05-2024

In the present study, we aim to perform a feasibility study to prove that 89Zirconium-bevacizumab PET scanning can indeed detect all small primary breast cancer lesions. Data from the present study may be used to design further studies with regard...

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

Summary

ID

NL-OMON35509

Source
ToetsingOnline

Brief title
VEGF imaging for early breast cancer detection.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, cancer of the breast

Research involving
Human

Sponsors and support

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

Intervention

Keyword: breast cancer, positron emission tomography, VEGF imaging

Outcome measures

Primary outcome

The primary endpoint will be 89Zr-bevacizumab tracer uptake in primary breast tumors

Secondary outcome

The secondary endpoint will be 89Zr-bevacizumab tracer uptake in axillary lymph nodes.

Study description

Background summary

Screening mammography is nowadays the single most effective method of early breast cancer detection. For screening of high risk individuals, the magnetic resonance imaging (MRI) technique is emerging. However, none of the above mentioned techniques has an optimal sensitivity and specificity, leading for instance to a significant portion of false positive results. The clinical consequence of this error is that additional tests and procedures are performed in women who may not have cancer.

Developing innovative visualization techniques based on essential alterations in breast cancer cells, are clearly desirable for optimizing early diagnosis of breast cancer. VEGF is a potent angiogenic growth factor, commonly involved in tumor-induced angiogenesis and is differentially expressed in normal versus (pre)malignant breast tissue. Non-invasive assessment of VEGF-levels in the micro-environment of the pre-malignant or malignant breast tumor could potentially be used as screening tool.

Study objective

In the present study, we aim to perform a feasibility study to prove that 89Zirconium-bevacizumab PET scanning can indeed detect all small primary breast cancer lesions. Data from the present study may be used to design further studies with regard to early breast cancer detection, and can potentially

support development of fluorescent optical imaging of VEGF as a screenings tool.

Primary objective
The aim is to perform a feasibility study to show that VEGF PET imaging using 89Zr-bevacizumab as tracer can be used for early breast cancer detection.

Secondary Objectives
A secondary aim is whether positive lymph nodes can be detected.

Study design

All patients will undergo a 89Zr-bevacizumab PET scan preoperatively at day 4 following tracer injection. The uptake of 89Zr-bevacizumab in the tumor will be quantified. Results will be fused and compared with standard imaging techniques and with standard tumor histology as well as specific tumor stainings for angiogenesis including VEGF staining. Sensitivity and specificity will be compared with conventional imaging.

Study burden and risks

There is a small change the patient devellops an allergic reaction on the tracer. Furthermore, a patient can devellop a haemotoma afer injection.

Contacts

Public
Universitair Medisch Centrum Groningen

Potbus 30.001
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Potbus 30.001
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a breast tumor who are scheduled to receive operative intervention either by means of a mastectomy or lumpectomy

Exclusion criteria

• Other invasive malignancy or condition which could affect compliance with the protocol or interpretation of results.
• Pregnant or lactating women.
• Prior radiotherapy on the involved area.
• Major surgery within 28 days before the initiation of the study.
• Clinically significant cardiovascular disease.
• Prior allergic reaction to immunoglobulins or immunoglobulin allergy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-10-2009
Enrollment:	47
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	89ZR-bevacizumab
Generic name:	89ZR-bevacizumab

Ethics review

Approved WMO Date:	05-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-11-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-08-2010
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	EUCTR2009-015838-29-NL
Other	n.a.
CCMO	NL29473.042.09