ProFaMa neoadjuvant: Diagnostic value of tumourmarkers measured in activated macrophages during neoadjuvant treatment of breast cancer.

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Research question and hypothesis Research questions1 Are there tumourmarkers available which can be measured intracellular by flowcytometry during neoadjuvant treatment of patients with breast cancer?2 Can we measure the effect of neoadjuvant...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON32754

Source
ToetsingOnline

Brief title
ProFaMa neoadjuvant

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde

Source(s) of monetary or material Support: Ministerie van OC&W,Beckton Dickinson

Intervention

Keyword: breast cancer, monitoring, neoadjuvant, tumourmarker

Outcome measures

Primary outcome

This research will focus on women with a locally or advanced carcinoma of the breast and who will receive neoadjuvant treatment in the Atrium Medisch Centrum in Heerlen. The primary outcome will be the changes in concentration of tumourmarker containing macrophages in relation to changes in tumour size as measured by MRI and pathologic respons.

Secondary outcome

not applicable

Study description

Background summary

Around 13,000 women will be diagnosed with invasive breast cancer each year in the Netherlands. Almost 1,300 women will be diagnosed with a ductal carcinoma in situ. Women have a 12 to 13 percent chance to develop a malignancy of the breast. Breast cancer is the most common type of cancer in the dutch female population. There has been a substantial decline in breast cancer mortality, and a major contributor is (neo)adjuvant medical therapy. Several arguments apply for chemotherapy in a so-called neoadjuvant treatment setting, prior to surgery. First, downstaging the tumour leads to less extensive resections and breast conservation becomes increasingly feasible. Second, micrometastases that may be present are thus treated at the earliest possible moment. A third advantage of neoadjuvant chemotherapy is that it enables the monitoring of treatment efficacy and makes it possible to identify markers of response to chemotherapy.
Accurate modalities for assessing chemotherapy response are critical to the evaluation and expansion of the use of neoadjuvant therapy for breast cancer. Conventional methods including clinical examination, mammogram, and breast

ultrasound are incorrect in identifying pathologic complete response patients in nearly half of the cases.
During the last decennia, several biomarkers have been identified which could be used for monitoring neoadjuvant treatment in women with breast cancer. Until now, none of these markers has had sufficient diagnostic accuracy to monitor neoadjuvant treatment. In this study, we want to investigate if measuring biomarkers inside activated macrophages by means of flowcytometric analysis can monitor the effect of neoadjuvant therapy.

Study objective

Research question and hypothesis

Research questions
1 Are there tumourmarkers available which can be measured intracellular by flowcytometry during neoadjuvant treatment of patients with breast cancer?

2 Can we measure the effect of neoadjuvant treatment of patients with breast cancer by flowcytometrical analysis of M30, CA 15,3, CEA and Her2 inside acrivated macrophages?

Hypothesis
1 Tumourmarkers as measured inside activated macrophages can ben measured by flowcytometry during neoadjuvant treatment of patients with breast cancer.

2 The flowcytometric measurement of M30, CA15,3, CEA and Her2 inside activated macrophages can monitor the effects of neoadjuvant therapy in patients witth breast cancer.

3 The flowcytometric measurement of CA15,3 and CEA inside activated macrophages can monitor the effects of neoadjuvant therapy in patients witth breast cancer more accurate than the measurements of CA15,3 and CEA in serum.

Study design

Prospective pilot-study in which a new diagnostic test, the measurement of tumourmarkers in activated macrophages, will be investigated.

Study burden and risks

The burden for the studygroup is very low. The course of the disease and treatment will not be influenced by this study.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men and women diagnosed with primary or recurring breast cancer who will receive neoadjuvant systemic therapy.

Exclusion criteria

Not being able to agree with the informed consent procedure.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-01-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-12-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL30514.096.09