The TESTBREAST study: early detection of breast cancer in women at high risk of developing breast cancer with serum biomarkers.

Published: 31-05-2017
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Early detecction of breast cancer in women with high risk of developing breast cancer with protein and glycan biomarkers.

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

Summary

ID

NL-OMON53091

Source
ToetsingOnline

Brief title
The TESTBREAST study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Genootschap Landgoed Keukenhof;Pink Ribbon;Zabawas;Fonds Nuts ohra;A Sisters Hope;Fonds Lisse-Bollenstreek

Intervention

Keyword: Biomarkers, Breast Cancer, High risk women: familial or BRCA or CHEK2 carriers), screening

Outcome measures

Primary outcome

Early detection of breast cancer by analysing protein and glycan profiles.

Secondary outcome

To analyse the prognostic value of protein and glycan profiles secundary

parameters are 5 years survival, disease free period and distant mestastasis

Study description

Background summary

There is need to improve screening for early detection of breast cancer. In population screening with standard mammography one out of five cancer cases is missed. In surveillance of (hereditary) high risk groups this number is even considerably higher (one in two) with high numbers of interval cancers reported and screen detected lesions with unfavorable size. Family history is one of the most influencing risk factors in breast cancer development.
Hereditary breast cancer accounts for up to 5-10% of all breast carcinomas with two high-penetrance genes (BRCA1 and BRCA2) responsible for about 16% of the familial risk of breast cancer cases and associated with an 60-80% lifetime risk for a mutation carrier. Early detection strategies are considered to address this heightened risk.
The purpose of a screening program is to identify breast cancer at an early stage before (regional) metastatic spread. The survival of women diagnosed with breast cancers <1 cm and with negative lymph nodes is excellent. In BRCA mutation carriers and in familial high-risk patients, tumor size at detection is a key predictor of survival and mortality risk may be reduced by early tumor detection. Early detection in high risk patients can improve survival time from 75% to 93%.(1)
Mammography has a low performance in this group with only 30-40% sensitivity.

The use of MRI next to mammography may improve the sensitivity of screening in women with a familial or genetic predisposition to breast cancer but the specificity is variable, the technique is time consuming and demanding and costs are high. In a recent study it was shown that 10% of the DCIS tumors were missed by using solely MRI data.(2)
A specific and more sensitive alternative to these image based techniques could be the use of proteomic or glycomic biomarkers

Study objective

Early detecction of breast cancer in women with high risk of developing breast cancer with protein and glycan biomarkers.

Study design

Serum samples are obtained from high risk women (familial or BRCA or CHECK2 mutation carriers) visiting the outpatient clinic for regular screening. On average 2 samples are colected per year, dependent on regular screeningmoments. The process of blood collection, storage en processing is standardized. De protein and/or glycan profiles in serum are analysed with 'Matrix- assisted Laser Desorption Ionization Time-Of-Flight' Mass Spectrometer(MALDI- TOF) or 'Matrix Assisted Laser Desorption Ionization Fourier Transform Ion Cyclotron Resonance' Mass Spectrometer (MALDI-FT-ICR) or Orbitrap. The obtained high throughput profiles are statistical evaluated.

Study burden and risks

The burden is multiple times vena punction (average of 2 times per year) and answer twelve multiple choice questions.

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

- women
- 25-75 years old
- indication for frequent surveillance (twice a year) because of genetic or familial high risk of developing breast cancer or life time risk of more 15 percent.

Exclusion criteria

- breast cancer in medical history
- malignancy in de past 10 years (excl. basalcell carcinoma)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	1193
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-06-2019

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	17-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	19-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	18-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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
Other	https://www.kanker.nl/trials/947
CCMO	NL59318.058.16