Early detection of breast cancer in women with a familial or genetic predisposition of developing breast cancer using biomarkers in serum

No registrations found.

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

Summary

ID

NL-OMON26238

Source
Nationaal Trial Register

Brief title
TESTBREAST study

Health condition

Breast cancer, hereditary breast cancer

Sponsors and support

Primary sponsor: Genootschap Landgoed Keukenhof, A Sisters Hope, Pink Ribbon, Zabawas, Nuts-Ohra
Source(s) of monetary or material Support: Genootschap Landgoed Keukenhof, A Sisters Hope, Pink Ribbon, Zabawas, Nuts-Ohra

Intervention

Outcome measures

Primary outcome

Analyzing the differences in protein profiles between patients and controls and within patients over time. Moreover, establishing a panel of protein-based biomarkers for the early detection of breast cancer.

Secondary outcome

The prognostic value of the selected protein profiles as biomarkers (5-year survival, disease free period and distant mestastasis)

Study description

Background summary

The purpose of a screening program is to identify breast cancer at an early stage before (regional) metastatic spread with the aim of improving the survival time of patients. However, currently, still a lot of cancer cases are missed. Especially in the high-risk group, mammography has a low performance and high numbers of interval cancers are being reported. The use of MRI next to mammography may improve the sensitivity in this group, but the specificity is variable, the technique is time-consuming and costs are high. Thus, there is a need to improve the screening for the early detection of breast cancer.
A specific and more sensitive addition to these imaging-based techniques could be the use of proteomic biomarkers. Therefore, in this study, the aim is to identify prediagnostic changes in protein biomarker levels between serial samples from the same study subject and between study subjects (cases and controls) and to identify a panel of protein-based biomarkers for the early detection of breast cancer in high-risk women. This will be studied by obtaining serum blood samples from high-risk women who visit the outpatient clinic for regular screening. On average, two samples will be collected every year, depending on the regular screening appointments. Protein profiles in serum will be analyzed using LC-MS.

Study objective

We expect that from a panel of possible protein-based biomarkers for the early detection of breast cancer, a small number of markers will be highly distinctive and able to detect breast cancer 1-2 years before diagnosis.

Study design

Every 6 months (during regular screening appointments) until disease onset and at the moment of cancer discovery

Intervention

Blood draw once every 6 months

Contacts

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Eligibility criteria

Inclusion criteria

- Women
- 25-75 years old
- Screening indication due to familiar or genetically enhanced risk of developing breast cancer or LTR > 15%

Exclusion criteria

- Previous invasive breast cancer in medical history
- Other malignancies within the last 10 years (other than basal cell carcinoma)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2017
Enrollment:	1250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	22-06-2020
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	NL8724
Other	METC Leiden Den Haag Delft (LDD) : METC 16.260 (CCMO: NL59318.058.16)

Study results

Summary results
N/A