

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26238

Bron

Nationaal Trial Register

Verkorte titel

TESTBREAST study

Aandoening

Breast cancer, hereditary breast cancer

Ondersteuning

Primaire sponsor: Genootschap Landgoed Keukenhof, A Sisters Hope, Pink Ribbon, Zabawas, Nuts-Ohra

Overige ondersteuning: Genootschap Landgoed Keukenhof, A Sisters Hope, Pink Ribbon, Zabawas, Nuts-Ohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Blood draw once every 6 months

Contactpersonen

Publiek

Leiden University Medical Center
Sophie Hagens

071-5265130

Wetenschappelijk

Leiden University Medical Center
Sophie Hagens

071-5265130

Deelnemers eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observatieonderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	30-05-2017
Aantal proefpersonen:	1250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	22-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
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NTR-new	NL8724
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Ander register METC Leiden Den Haag Delft (LDD) : METC 16.260 (CCMO: NL59318.058.16)

Resultaten

Samenvatting resultaten

N/A