

Early detection of Hereditary Breast Cancer by Monitoring MicroRNA expression in Nipple Aspirate Fluid

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Predictive value of biomarkers in early breast cancer development, with a primary focus on miRNA.

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

Samenvatting

ID

NL-OMON24687

Bron

Nationaal Trial Register

Verkorte titel

NAF study

Aandoening

Breast cancer, hereditary breast cancer

Ondersteuning

Primaire sponsor: Vrienden UMC Utrecht

Overige ondersteuning: Vrienden UMC Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Predictive value of biomarkers in early breast cancer development, with a primary focus on

miRNA.

- To establish biomarker profiles in NAF, follow them in time and establish a correlation with breast cancer development.
- To determine threshold values of these biomarkers that point to a significant risk of imminent breast cancer development thereby indicating the right time of prophylactic breast surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Breast cancer develops by the stepwise accumulation of interacting epigenetic and genetic events over time. While genetic events are specific processes that differ greatly between patients, epigenetic events are more generally occurring in breast cancer development. Therefore, epigenetic monitoring (in addition to genetic monitoring) could be a breakthrough in breast cancer prevention. Diagnostically there is a need for better procedures that will predict accurately who will and who will not develop breast cancer. MicroRNAs (miRNAs) are small, non-protein-coding RNAs (~18-25 nucleotides in length) that regulate gene expression on a post-transcriptional level by binding to and thereby suppressing specific target mRNAs. In this project we aim to assess the occurrence and changes over time of miRNA expression levels in NAF of women at high risk for breast cancer to determine risks and correct timing of interventions. The current evidence indicates that miRNAs, present in all human body fluids, have the potential to act as biomarkers of malignancy, as they show high accuracy in identifying different tumor types. With that in mind, we are in the process of establishing a Biobank of blood samples of women at increased breast cancer risk to be able to determine the usefulness of biomarkers in blood, and their correlation with results from NAF.

Objective: To establish biomarkers in NAF, follow them in time and link them to breast cancer development at its earliest stage in women at high risk for breast cancer. Threshold values of biomarkers will be determined that point to a significant risk of imminent breast cancer development, thereby indicating the right time of prophylactic breast surgery in these high-risk women.

Doel van het onderzoek

Predictive value of biomarkers in early breast cancer development, with a primary focus on miRNA.

Onderzoeksopzet

0, 6 months, 12 months, 18 months before disease onset

Onderzoeksproduct en/of interventie

A onetime dose of 4 IE oxytocin nasal spray is administered prior to the nipple fluid aspiration (NFA) procedure. Nipple fluid is obtained through the use of a manual assisted vacuum-system. After subject's approval, three vials of blood for biobanking will be taken.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- > 20% lifetime risk of developing breast cancer (e.g. due to germline mutations such as BRCA1 or BRCA2)
- Previous DCIS/invasive breast cancer
- Female $\geq$ 18 years of all ethnic backgrounds

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Bilateral ablative breast surgery
- Bilateral breast reduction with nipple graft
- Pregnancy or lactation
- Active breast infection
- Disseminated breast cancer

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, 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:	26-05-2008
Aantal proefpersonen:	620
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	25-05-2020
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
NTR-new	NL8661
Ander register	METC UMC Utrecht : METC 06-091 (CCMO: NL11690.041.06)

Resultaten