Breast Cancer Biomarkers in Nipple Aspirate Fluid and Blood in Healthy Women

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

Summary

ID

NL-OMON47370

Source
ToetsingOnline

Brief title
Nipple Aspirate Fluid and Blood in Healthy Women

Condition

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

Synonym
breast cancer, breast malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: A sister's hope via Stichting Vrienden UMC

Utrecht

Intervention

Keyword: Bloed, MicroRNA, Nipple aspirate fluid, Screening

Outcome measures

Primary outcome

- To evaluate miRNA expression levels in NAF of healthy volunteers to determine

a baseline that will lead to cutoff values for the detection of breast cancer.

- Finding the best endogenous control for real-time quantitation of miRNAs in

NAF.

- To evaluate miRNA expression levels in blood of healthy volunteers to

correlate the results in NAF to those in paired serum and/or plasma.

Secondary outcome

- Evaluate the feasibility of performing RNA sequencing in NAF.

- Evaluate exosome extraction from NAF and asses miRNAs in NAF-derived exosomes

- To assess discomfort, uncertainty and distress experienced by subjects

undergoing NFA by means of a questionnaire.

Study description

Background summary

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, like aberrant microRNA expression, 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. In this project we aim to assess miRNA expression in nipple aspirate fluid and blood in healthy

women.

Study objective

To be able to assess the value of new markers, we first analyze these potential markers in nipple aspirate fluid and blood from healthy women. The main goal of this study is to evaluate the normal expression levels of microRNAs in NAF and blood to determine baselines that will lead to cut-off values for the detection of breast cancer. The results will be compared with microRNA levels obtained just before primary surgery from patients with suspicion of, or histologically proven, breast cancer. We will perform stability analysis of candidate endogenous controls, and choose a microRNA that then can be used as endogenous control for real-time quantitation of miRNAs in NAF and blood in healthy subjects, women at high risk of developing breast cancer and breast cancer patients. We want to explore the feasibility of performing RNA sequencing in NAF to identify new potential biomarkers in the future and we evaluate exosome extraction from NAF and assess miRNAs in NAF-derived exosomes.

Study design

This study has a cross-sectional design and healthy women will be included. Nipple fluid will be obtained one time and the women will not be followed in time. A one time dose of 4 IE oxytocin nasal spray is administered prior to the nipple aspiration procedure. Nipple fluid is obtained through use of a vacuum-system. A questionnaire is filled out before and after the nipple fluid aspiration procedure.

Study burden and risks

The data obtained in healthy volunteers will allow us to improve our program that monitors development of epigenetic changes in nipple aspirates in women at high risk for developing breast cancer to optimally time preventive breast surgery. This will allow on one hand postponing or avoiding a mutilating operation in these high risk women as much as possible (reducing morbidity), while on the other hand preventing development of invasive breast cancer (reducing mortality). Oxytocin-supported nipple aspiration is very well tolerated as has been demonstrated in our previous study.

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

- Female
- Healthy
- Non-lactating
- * 45 years

Exclusion criteria

- Male
- Age under 45 years
- Pregnancy or lactating
- Active breast infection
- Bilateral ablative breast surgery
- Bilateral breast reduction with nipple graft
- Personal history of DCIS or invasive breast cancer
- > 20% risk of developing breast cancer

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2013
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	05-08-2015
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	08-06-2017
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	18-05-2018
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	12-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-06-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL41845.041.12