Biomarker detection for benign breast diseases and primary breast cancer by serum and tissue protein profiling.

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

Summary

ID

NL-OMON30316

Source
ToetsingOnline

Brief title
Breast Cancer Proteomics study (BCP study)

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
benign breast diseases, breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Slotervaartziekenhuis

Intervention

Keyword: benign breast disease, biomarkers, breast cancer, proteins

Outcome measures

Primary outcome

Primary study outcomes are:

a. differences in protein profiles between serum samples and tissue specimens

of patients with benign breast disease and breast cancer patients,

b. differences in protein profiles between serum samples of benign breast

disease and breast cancer patients, and between specimens of normal, benign and

tumourous tissue.

c. intra-individual differences in protein profiles in serum withdrawn before,

directly after and one month after surgery of patients with benign breast

disease or breast cancer.

Secondary outcome

Not applicable.

Study description

Background summary

Breast cancer accounts for one third of all new cancer cases among women in The Netherlands. About 36% of these women will ultimately die because of this disease. Detecting early stage cancer by pre-symptomatic screening can greatly reduce breast cancer-related mortality. Currently used methods (mammography, CA15.3), however, still lack adequate sensitivity and specificity. In a pilot study conducted earlier, we identified several serum biomarkers for breast cancer, using the Surface Enhanced Laser Desorption Ionisation Time-of-Flight Mass Spectrometry (SELDI-TOF MS) technique. Knowing the origin of these biomarkers will greatly aid in understanding the pathogenesis of breast cancer. Both invasive cancer and premalignant lesions (benign breast diseases) have

been demonstrated to share several genetic alterations. We therefore hypothesize that protein expression, as a genome derivative, will to some extend be homologous in both premalignant and malignant tissue. Possibly, benign breast diseases share a certain serum and tissue protein expression profile with invasive breast carcinoma. When structurally identified, these specific proteins can provide further insight into the molecular development of breast cancer.

Study objective

The study objectives are:
1. Getting insight into the biological origin of the typical serum protein profile in breast cancer by comparing the protein profiles in breast tissue of benign breast disease patients and primary breast cancer patients with the corresponding serum protein profiles.
2. Investigating the presence of homologous proteins, or specific, differentially expressed proteins in:
a. serum of benign breast disease and breast cancer patients, and
b. normal, benign diseased, and cancerous tissue,
to gain more insight into the molecular development of breast cancer.
3. Investigating the effect of surgery on the serum protein profile of benign breast disease patients and primary breast cancer patients. This might also give us more insight into the origin and the conditions under which the discovered protein profiles emerge.
4. Determination of a possible correlation between biomarkers and co-morbidity, co-medication and patient-depending variables such as age, to determine appropriate stratification or adjustment for the analysis.

Study design

Prospective follow-up study.

Study burden and risks

All serum samples will be obtained along with samples for routine clinical chemical laboratory assays. Tissue specimens of breast tumours, benign breast diseases, or normal breast tissue will be obtained during surgery (e.g. lumpectomy, mastectomy of breast reduction surgery). Since withdrawal of serum and tissue is performed within the compass of treatment, no additional inconvenience is posed on these patients.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Female patients diagnosed with benign breast disease or primary breast cancer (that will be treated surgically) by breast biopsy at the Department of Surgery of the Slotervaart Hospital in Amsterdam.
2. Female patients diagnosed with benign breast disease and treated surgically the Department of Surgery of the Slotervaart Hospital in Amsterdam.
3. Female patients undergoing breast reduction surgery at the Department of Plastic Surgery of the Slotervaart Hospital in Amsterdam.
4. Age > 18yrs.
5. Able and willing to undergo blood and tissue sampling for protein analysis.

Exclusion criteria

1. Known history of (treated) malignancies.
2. Incapacity of participant to give written informed consent.
3. Patients not able to undergo blood and tissue sampling for protein analysis.

4. Any psychological, familial, sociological or geographical condition that may potentially interfere with compliance to the study protocol.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	380
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL14905.048.06