BASIS (Breast Cancer Somatic Genetics Study)

Published: 21-05-2012
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The BASIS study will analyze the full cancer genome of breast cancer subtype ER+ HER2-.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON37355

Source
ToetsingOnline

Brief title
BASIS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breastcancer; breastcancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: seventh framework programme; European union

Intervention

Keyword: Breast cancer, Full genome sequencing, Methylation

Outcome measures

Primary outcome

Full genome DNA sequencing and RNA expression profiling. Potential cancer genes

will be further analyzed by using in situ hybridization and RT-PCR.

Secondary outcome

Full genome methylation analysis will be performed.

mRNA en miRNA expression profiling

Study description

Background summary

The BASIS (Breast Cancer Somatic Genetic Study) study focussses on the full genome sequencing of tumor and normal DNA of 500 breast cancer patients. It is suggested that malignant tumors develop from somatic genetic mutations presenting during life. These mutations may alter important functions of proto-oncogenes. The understanding of the genetic mutations leading to cancer can make early detection, prevention and effective therapy possible.
The BASIS study is part of the ICGC (International Cancer Genome Consortium) organization, which is involved in generating catalogues of different cancer types. BASIS focusses on studying breat cancer subtype ER+ HER2-; this subtype is the most common type of breast cancer (approximately 40%). Results of the BASIS study will be catalogued by the ICGC model. In this study 500 tumors will be analyzed by using shotgun genome sequencing an compared to normal DNA collected from the same patient. With this technique all deletions, insertions, copy number changes, translocations and other chromosomal alterations can be detected. Also full genome DNA methylation analysis will be performed on our samples; as mRNA and miRNA expression profiling.
All data will be coded and rapidly made available for other researchers. This broad and complex study together with other ICGC studies gives insights in one of the most common diseases in the developed world and gives new possibilities in respect to prevention, early detection and new therapies.

Study objective

The BASIS study will analyze the full cancer genome of breast cancer subtype ER+ HER2-.

Study design

The development of a catalogue containing genetic information of ER+ HER2-breast cancer is a prospective multicenter study called BASIS. As a part of the BASIS study, the academic medical center (AMC) is involved in collecting the samples for analyzing:
- Full genome sequencing of the tumor and normal tissue of the same patient
- Potential cancer genes will be further analyzed by using in situ hybridization and RT-PCR
- Full genome methylation analysis will be performed
- Finally mRNA and miRNA expression profiling will be done
Collected samples will be coded in the AMC. In future state, only the AMC can link the coded information to a patient (for example in case of patients pulling out of the study or the follow-up). After all samples and patient information is coded by its unique code, it will be send to the Sanger Center. The Sanger Center will analyze the samples or will further distribute the samples to other members of the BASIS project.

Study burden and risks

Physical risk known for vene punction

Privacy and security risk: There is a very low risk that in the end genetic information of the BASIS project can be linked to other databases containing genetic/medical information. It is possible although véry unlikely that the security of a computer containing the database is hacked or damaged. Nó insurance company, employers or other familymembers have any insights in the personal medical information of the patient.

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

The tumorsubtype is ER+ HER2-
Tumor has to be removed surgically

Exclusion criteria

Tumor has been treated with preoperative radiation and/or chemotherapy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO Date:	21-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL39840.018.12