MAMma-ablation ECG study

Published: 18-10-2013
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To establish the role of breast tissue on ECG recordings in asymptomatic women, without prior CVD, before and < 6 weeks after ablation of the left (or both) breasts.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38789

Source
ToetsingOnline

Brief title
MAM ECG study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
electrocardiology

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast ablation, Electrocardiografy, Woman

Outcome measures

Primary outcome

The goal of this study is not to establish whether there is a significant difference between the ECG recorded before and after ablation, as there will be surely an effect, but to examine the nature of this change. Further, to identify to what extend the differences in ECG recordings between men and women are caused by differences in thorax geometry. For such a type of study it not possible to determine beforehand the sample size needed to obtain a significant result by power calculation (indeed, the phrase "significant" does not apply).
In order to reach the goal of this study there is no need for a large sample size, but the size should be large enough to avoid a strong effect of possible outliers. Our aim is to include 30-40 women in this study. For each ECG/posture measurement a reconstructed body surface will be available. These reconstructions will be registered to enable:

- Changes in breast tissue due to ablative surgery
- Changes in electrode position for the subsequent follow up measurements.

ECG analysis will take into account the changes in P-wave, QRS and T- wave morphology.

Secondary outcome

nvt

Study description

Background summary

Sex differences in several baseline characteristics of electrocardiograms (ECG) are well known, but the clinical significance often remains unclear. These concern amplitudes and duration as well as repolarization patterns of the ECG. Most important gender-disparities in baseline ECG recording concern a longer QT-interval and a longer and more horizontal RS-T segment in women compared to men. The etiology of this *gender-repolarization-gap* has been puzzling cardiologists until now. It has been proposed that testosterone-levels are related to a shorter QTc in adult men, while estrogens interfere with potassium and calcium channels in females. However, no significant cyclic variation in ECG patterns have been found in females and conflicting reports have been published on the association between ECG changes with menopausal status or hormone use.
Other important factors that affect gender-differences in ECG recordings are related to their different thorax size and presence of adipose tissue. Breast tissue in women, dependent on breast size and shape as well as adipose tissue in obese patients lead to lower QRS and T-amplitudes with an increase of the QRS complex after mastectomy. Breast tissue in women often leads to incorrect positioning of the precordial leads that may affect the quality of ECG recordings.
As primary clinical decision rules in acute and chronic settings of cardiology are importantly based on interpretation of baseline ECG recordings, misinterpretation of ECG*s frequently occur in females patients. This often results in unnecessary further diagnostic testing, especially since advanced non-invasive cardiac imaging techniques are available (CT scans, MRI imaging, PET-CT). This has contributed to the giant raise in costs of healthcare over the past decennia. Moreover, these advanced imaging techniques have reduced technical skills of young doctors in ECG reading and interpretation, while the ECG has remained the first important step in the diagnostic cardiology process.

Study objective

To establish the role of breast tissue on ECG recordings in asymptomatic women, without prior CVD, before and < 6 weeks after ablation of the left (or both) breasts.

Study design

All patients scheduled for ablation of the left (or both) breasts will be invited for an ECG recording before and < 6 weeks after elective surgery, as has been developed by the department of Medical Physics at the UMC St Radboud. Both ECG recordings will be analyzed so patients can be used as their own reference. The ECG recorded will either be the standard 12 lead ECG and a Body surface map (BSM). As this study will investigate the changes in the ECG due to changes in body shape, the body surface needs to be measured accurately. For this purpose a 3D camera will be used to create accurate 3D reconstructions of the body surface during each ECG measurement with the ECG electrodes attached.

To be able to compare the individual ECG changes, the same electrode positions should be used for all the ECG measurements on one patient. The first reconstruction of the body surface will be used for this purpose. From these scans the changes in body shape can be analyzed as well. The reconstructed body surface can be used as a reference.

Before the initiation of this study, the Institutional Review Board of the UMC St Radboud in Nijmegen will be asked permission. Patients will be informed about the procedure of the ECG recordings before and after surgery.

Study burden and risks

nvt

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

All women who are scheduled for an elective ablation of the left breast are eligible to participate. Women who are scheduled for ablation of both breasts or who previously had an ablation of the right breast are also candidates for inclusion.

Exclusion criteria

Women with ulcerating, late stage breast cancer will not be asked to participate.
Prior CVD. Cardiovascular complaints.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL45741.091.13