Surface vs Subcutaneous ECG study

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The primary objective involves comparison of the sensing performance of surface and subcutaneous ECGs at rest, and comparison of sensing performance of surface and subcutaneous ECGs during exercise.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30295

Source
ToetsingOnline

Brief title
SUSE

Condition

- Other condition
- Cardiac arrhythmias

Synonym
not applicable - ECG diagnostics

Health condition

ECG diagnostiek

Research involving
Human

Sponsors and support

Primary sponsor: Vitatron
Source(s) of monetary or material Support: Vitatron B.V. (als onderdeel van Medtronic)

Intervention

Keyword: Comparison, Reveal® Plus, Subcutaneous ECG, Surface ECG

Outcome measures

Primary outcome

The sensitivity of the R-wave detection and the Positive Predictive Value are the indicators for the quality and sensing performance of different ECG signals.

Secondary outcome

Signal to noise ratio as well as morphology metrics will be analyzed to asses signal characteristics of the various ECG signals and compare the different signal characteristics. The parameters for the morphology analysis are not fully defined at this time. These will include but are not limited to QRS complex morphology, amplitudes of the different components of the QRS complex, P-waves and T-waves and will be further defined during the analysis.

Study description

Background summary

This study will be conducted in order to investigate the difference between the subcutaneous ECG signals recorded by the Reveal® Plus Insertable Loop Recorder (ILR) system and surface ECG signals recorded by a DR180+ Digital Holter Recorder (external Holter). Insight will be obtained on the influence of motion artifacts on surface ECG and subcutaneous ECG signal recordings.
The outcome of this study is expected to support the use of surface ECG signals to test ILR detection algorithms. Furthermore, demonstration that surface ECG signal recordings (obtained via an external Holter) are a good surrogate for subcutaneous ECG signal recording by the ILR, will support the pre-implant mapping procedure, which is used to find the most optimal orientation of the ILR to ensure optimal sensing.

Study objective

The primary objective involves comparison of the sensing performance of surface and subcutaneous ECGs at rest, and comparison of sensing performance of surface and subcutaneous ECGs during exercise.

Study design

The SUSE study is a prospective, non-randomized, multi-center, post-market study.
The study consists of one visit only during which patients with a Reveal® Plus ILR will be connected with a DR180+ Digital Holter. During an in-office procedure the surface ECG signals will be recorded via the DR180+ Digital Holter Recorder and the subcutaneous ECG signal will be recorded with the Reveal® Plus ILR. This will be done while the patients are in different positions (rest) and during specific movements (exercise).

Study burden and risks

The study-related procedures are expected to prolong subject*s standard Reveal®-related visits (e.g. follow-ups) by 20 minutes and are considered to entail minimal risk. The potential risks to a subject are believed to be the same as those encountered during standard ECG testing or Holter recording. The risks involved in this study include but are not limited to irritation or an allergic reaction to the adhesive used to secure the surface electrodes to the skin.
There are no direct benefits for participating subjects.

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

- Minimum age of 18 years
- Reveal® Plus ILR implantation at least 6 weeks ago

Exclusion criteria

- Patient is not able to perform physical maneuvers with the hands and arms,
- Patient is not able to walk,
- Patient is not able to stand,
- Patient is participating in a study that is expected to compromise the results of this study,
- Patient has an allergy against the adhesive Lead-Lok electrodes.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO Date:	09-02-2007
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL15147.094.06