Algorithm verification STudy with an External Reveal (Investigationel Xt)

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

Summary

ID

NL-OMON30087

Source
ToetsingOnline

Brief title
ASTERIX

Condition

- Cardiac arrhythmias

Synonym
Atrial arrhythmias, heart rhythm disturbances

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AF detection, Algorithm, Reveal XT, Verification

Outcome measures

Primary outcome

To evaluate the performance of the detection algorithms for detecting episodes of atrial tachyarrhythmia (including atrial fibrillation, atrial flutter, and atrial tachycardia) with a duration of at least 2 minutes, compared to the detection possible using a 48 hour Holter recording.

Secondary outcome

To compare AF burden determined using the S-Spare compared to the 48 Hour Holter

To compare the detection performance of the algorithms for all atrial tachyarrhythmia episodes

To compare the detection performance of the algorithms for episodes of atrial fibrillation

To compare detection performance of the algorithms for episodes of other atrial tachyarrhythmia

To investigate Sensitivity, Specificity, and PPV of the algorithm under the studied conditions on a per patient basis

To investigate Sensitivity, Specificity, and PPV of the algorithm under the studied conditions over all episodes of all patients

To investigate the variance of R-wave sensing intra- and inter-individually

Study description

Background summary

This study is conducted in order to validate newly developed algorithms to permanently detect and monitor AF. It is believed that information about the frequency and amount of AF in an individual patient may augment the treatment for a patient suffering from paroxysmal AF. Useful AF related diagnostic parameters to optimize patient treatment are e.g. AF burden, number of episodes, duration of AF episodes, etc. Unfortunately these parameters are difficult to assess without continuous monitoring, as even in symptomatic patients with AF, the majority of AF-episodes go unnoticed by the patient [1, 2, 3]. This gives rise to the current situation where symptoms and patient history are of limited value for the diagnosis and follow-up of AF.

Study objective

The objective of the study is to investigate the performance of the arrhythmia detection algorithms that will be built into the Reveal XT® insertable loop recorder. The Reveal XT® detection algorithms are designed to detect atrial tachyarrhythmias, as well as ventricular tachyarrhythmias and bradycardia. In this study the specific performance of the detection algorithms for detecting episodes of atrial fibrillation and atrial tachycardia (including atrial flutter) with a duration of at least 2 minutes will be investigated by means of an external device.

Study design

The ASTERIX Study is a pre-market, non-randomized, open-label, multi-center explorative study.

Study burden and risks

This study is considered to entail minimal risk. The potential risks to a subject are expected to be the same as those encountered during standard ECG testing or Holter recording.

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

•Patient is willing to wear two external recording devices for a 48 hour period;
•Patient is willing to give his/her informed consent;
•Patient fulfills at least one of the following:
- Patient has atrial fibrillation or flutter with an indication for pharmacological cardioversion;
- Patient has atrial fibrillation or flutter with an indication for electrical cardioversion;
- Patient is scheduled for cardiac valve surgery or has undergone cardiac valve surgery maximally 2 days previously;
- Ambulatory patient who will undergo pulmonary vein ablation or atrial flutter ablation;
- Ambulatory patient who has undergone pulmonary vein ablation or atrial flutter ablation at least two months previously, with currently suspected recurrence of atrial fibrillation or flutter;
- Ambulatory patient with suspected paroxysmal atrial fibrillation or other atrial tachyarrhythmia.

Exclusion criteria

• Patient has an implanted pacemaker or ICD
• Patient has an allergy against adhesive ECG electrodes
• The study will interfere with a therapeutic or diagnostic procedure which is planned or expected within the 48 hour study period
• Patient is a minor, legally incompetent, or does not meet other local requirements for participation in a clinical study

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-01-2006
Enrollment:	230
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-07-2006
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	NL12605.094.06