Holter (for) Risk Recognition & Conversion (of) life-threatening events (into survival)

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Demonstrate that a risk score, based on non invasive long term ECG, can predict the absence of arrhythmias requiring ICD intervention or the absence of sudden death, with a >90% certainty (NPV) in patients with a reduced LVEF currently qualifying...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON56823

Source
ToetsingOnline

Brief title
Horracles

Condition

- Cardiac arrhythmias

Synonym
Reduced Left Ventricular Ejection Fraction; reduced heart function

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Group Nederland NV
Source(s) of monetary or material Support: Sorin Group

Intervention

Keyword: ICD implantation, Prediction, Risk score

Outcome measures

Primary outcome

The absence of arrhythmias requiring ICD intervention or the absence of sudden death

Secondary outcome

Demonstrate that heart failure hospital admission / cardiac death can be predicted by non invasive methods in patients with a reduced LVEF currently qualifying for primary ICD implantation.

Show that slow VT as recorded by the ICD is associated with heart failure development/ cardiac death

Show that safeR is not associated with ventricular pacing during follow-up

Prospectively demonstrate that very low LVEF values (30% and less) are predictive for future ICD intervention in patients currently qualifying for primary ICD implantation with contemporary infarction and heart failure therapy.

Study description

Background summary

Today patients are selected for preventive ICD implantation (also called primary indication) when the risk of sudden death is considered excessive as compared to not receiving an ICD. It is not always certain if the patient indeed benefits from this ICD implantation. It is very well possible that a patient who received an ICD would eventually not have needed this implantation (over many years he/she would not has arrhythmias requiring a therapy delivery

from the ICD). However, ICD in primary prevention saves lifes. Physicians and insurance companies are dealing in different ways with the European guidelines for a preventive ICD implantation because of various medical and economic reasons.

Study objective

Demonstrate that a risk score, based on non invasive long term ECG, can predict the absence of arrhythmias requiring ICD intervention or the absence of sudden death, with a >90% certainty (NPV) in patients with a reduced LVEF currently qualifying for primary ICD implantation.

Study design

A non-randomized prospective clinical observational multi-centric trial.

Intervention

Patients identified as per the guidelines will receive an ICD.

Study burden and risks

The benefits of this trial are that the patient will receive extensive attention after ICD implantation. Furthermore, participation will contribute to the improvement of patient care via the development of a predictive score that could improve the selection of future patient who will benefit of ICD treatment. This score could also avoid unnecessary ICD implantation in certain patients.

There are no foreseeable anticipated increased risks associated with the use of Holter recorders. The Holter recorder is a non-invasive tool and is commercially available.

There are no foreseeable anticipated increased risks associated with implantation of the PARADYM ICD (CE Mark approved) compared to other commercially available ICD devices.
Furthermore, participation in this study does not involve any additional risks for the patient, as he/she is already scheduled for an ICD implantation.

In case the patient is a woman of childbearing potential she has to use anticonception for the duration of the study. Breastfeeding is prohibited.

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

- Criteria for prophylactic ICD according to guidelines in patients with reduced LVEF
- Written informed consent
- Scheduled for implant of a PARADYM 8550 or PARADYM 9550

Exclusion criteria

1. Under the age of 18 years old
2. Presence of a permanent pacemaker or previous ICD
3. Permanent AF
4. NYHA IV
5. Within 8 weeks of infarction or within 3 months of coronary revascularization

6. Patient requiring permanent amiodarone or antiarrhythmic drugs.
7. Specific familial or genetic based arrhythmias.
8. ARVC, HCM, or severe valvular disease
9. CRT indication (European guidelines)
10. Renal hemodialysis
11. Recipient of cardiac transplant
12. Pregnancy
13. Advanced malignancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2011
Enrollment:	195
Type:	Actual

Medical products/devices used

Generic name:	Implantable Cardioverter Defibrillator Paradym 8550;Implantable Cardioverter Defibrillator Paradym 9
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-03-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL33039.100.10