Deceleration capacity and heart rate turbulence in decompensated heart failure patients (DECIDE-HF)

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The study is being conducted to evaluate whether continuous measurements of Heart Rate Turbulence (HRT), Deceleration Capacity (DC) and Acceleration Capacity (AC) can be used to predict decompensation in Heart Failure patients.Software algorithms...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON32997

Source
ToetsingOnline

Brief title
DECIDE-HF

Condition

- Heart failures

Synonym
failure of heart function, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic BV

Intervention

Keyword: changes heart rhythm, decompensation, heart failure, predictors

Outcome measures

Primary outcome

Het gecombineerde primaire eindpunt is hartfalen gerelateerde hospitalisatie en hartfalen gerelateerd overlijden.

Secondary outcome

• Find the best combination of HRT-TO, HRT-TS, DC and AC to differentiate between the state of a patient at baseline and at during HF related hospitalization/death.

• Determine the optimal threshold settings (fixed or adaptive) for the algorithm, in case it would be used to alarm the patient/physician for HF decompensation.

• Determine the correlation between the Optivol parameter (alert in case of fluidretention in lungs) and the HRT/DC/AC parameters.

• Determine the correlation between bodyweight and the HRT/DC/AC parameters.

• Characterize the incidence of premature heart contractions (PVCs) in Heart Failure patients.

• Asses preditive value of HRT/AC/DC in relation to ventricular tachycardias (VT/VF episodes)

• Determine the correlation between the HRV, Activity, Night HR, VT and AF parameters, AF parameters (available by default via Cardiac Compass), and the HRT/DC/AC parameters.

Study description

Background summary

The underlying mechanism of the worsened heart-rate regulation in heart failure patients is largely unknown. Patients at risk at risk for sudden cardiac death (after myovardial infaction) show an altered compensatory response of the autonomic nervous system after a premature heart contraction. Moreover, heart failure is associated with a higher heart rate variability. Deceleration capacity (DC), acceleration capaciteit (AC) en heart rate turbulence (HRT) can be computed from the ECG-signal and characterize the status of the autonomic nervous system.

Research has indicated that for instance HRT is an independent predictor of death by heart-failure decompensation in patients with moderate to severe heart failure. Also, HRT relates to functional debilitation (NYHA class) of the patient. The DECIDE-HF study is unique in investigating the temporal changes in these parameters within a group of heart failure patients.

Study objective

The study is being conducted to evaluate whether continuous measurements of Heart Rate Turbulence (HRT), Deceleration Capacity (DC) and Acceleration Capacity (AC) can be used to predict decompensation in Heart Failure patients.

Software algorithms will measure the state of the compensatory mechanism of the autonomic nervous system that is related to the heart. If this relates to worsening heart failure, the algorithms can be incorporated as a monitoring system in ICDs and pacemakers. An early warning system may alert patients and physicians in case of heart failure worsening. treatment may be adapted in a early stage to prevent hospitalization or a further worsening in health.

Study design

This is a multi-center, non-randomized, chronic feasibility study with investigational download software (RAMware). Maxmally 60 patients will participate in maximally 5 european centers. We expect the study to start in august 2009 with a duration between 18 to 30 months. The individual patient will participate between 12-24 months. Regular practice of the hospital will be followed so we will not perform extra study-related visits.

Intervention

none

Study burden and risks

• There will be no extra study-related follow-up visits in the hospital
• Patients receive a weighing scale and will be asked to register their weight daily in a logbook
• The research software possibly uses more battery as a result of which the ICD may have to be replaced 4 weeks earlier kunnen
• other risks that are as yet unforeseen
• A future monitoring system may be incorporated in ICDs and pacemaker. This would alerts patients and physicians in an early stage of heart failure worsening. Treatment may be adapted in a early stage to prevent hospitalization or a further worsening in health.

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

1) Dual or triple chamber ICD/CRT-D device implanted for more then 1 month (the device is a Secura® DR, Consulta® CRT-D, Concerto® II CRT-D, Virtuoso® II DR, Maximo® II DR or a Maximo® II CRT-D; at least one sensing lead in the right atrium and one lead in the right ventricle.
2) Systolic Heart Failure and is at the moment of enrollment in NYHA class II or III
3) Linker ventriculaire ejection fraction of less than 40%
4) Patient has had a HF-related hospitalization in the past 12 months
(see protocol p.9)

Exclusion criteria

The patient:
1) needs permanent atrial pacing (>10%)
2) requires additional RAMware downloads after study enrollment
3) has (intermittent) 2nd or intermittent 3rd degree block
4) has persistent or permanent Atrial Fibrillation
5) has had recent (< 2 months) acute coronary syndrome or revascularization
(see protocol p.9-10)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	ICD with new software
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL29069.042.09