Early detection of heart decompensation by intrathoracic impedance monitoring by means of the OptiVol Patient Alert(TM) in Medtronic(R) InSync Sentry(TM) ICDs

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To investigate the clinical value of OptiVol (TM) impedance measurement by Medtronic(R) InSync Sentry(TM) ICD's. We aim to determine specificity and sensitivity for detecting heart failure. With collected data we want to design a protocol for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30764

Source
ToetsingOnline

Brief title
OptiVol Patient Alert(TM) study

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: cardiac resynchronization therapy, chronic heart failure, intrathoracic impedance

Outcome measures

Primary outcome

number of true positive OptiVol (TM) alarms

Secondary outcome

not applicable

Study description

Background summary

Decompensated heart failure is an important reason for hospitalisation in patients with chronic heart failure. It is associated with an increased morbidity and mortality. Scientific research has proven that intrathoracic impedance measurement is able to detect decompensation in a preclinical phase. This was reason for Medtronic (R) to implement a feature to measure impedance in InSync Sentry (TM) ICD's. In literature little is known about the clinical value of this feature.

Study objective

To investigate the clinical value of OptiVol (TM) impedance measurement by Medtronic(R) InSync Sentry(TM) ICD's. We aim to determine specificity and sensitivity for detecting heart failure. With collected data we want to design a protocol for clinical practice.

Study design

Patients who have a Medtronic(R) InSync Sentry(TM) ICD will be included in our study after informed consent. The OptiVol (TM) feature enabling impedance measurement will be activated and at baseline data is collected (blood sample, electrocardiography, transthoracal echocaradiography, chest X-ray and ICD

check-up). During follow-up patients will be reassesed in case of a OptiVol alarm or in case of heart failure.

Study burden and risks

not applicable

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

chronic heartfailure of any cause
implantation of Medtronic(R) InSync Sentry(TM) ICD

Exclusion criteria

impossibility to give informed-consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2007
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2007
Application type:	First submission
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	NL14316.060.06