

# 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...

|                              |                        |
|------------------------------|------------------------|
| <b>Ethical review</b>        | Approved WMO           |
| <b>Status</b>                | Recruitment stopped    |
| <b>Health condition type</b> | Heart failures         |
| <b>Study type</b>            | 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, transthoracic echocardiography, chest X-ray and ICD

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

### **Study burden and risks**

not applicable

## **Contacts**

### **Public**

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### **Scientific**

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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 |