Patient Status Self-EvaluatioN throuGh Exercise and sonR

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The primary objective of the PASSENGER study is to investigate any relationship between changes in SonR1 augmentation and a change in patients* exercise capacity as assessed by the 6 Minute Walk Test.

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON41210

Source
ToetsingOnline

Brief title
PASSENGER

Condition

- Heart failures

Synonym
Heart failure, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Group Nederland N.V.
Source(s) of monetary or material Support: Sorin Group

Intervention

Keyword: CRT-D, Exercise test, SonR

Outcome measures

Primary outcome

The primary endpoint of the study is to investigate any relationship between changes in the SonR1 augmentation and a change in the exercise capacity of CRT patients as assessed by the 6MWTbetween follow-ups

Secondary outcome

- Assess that for 10 out of the 15 first patients enrolled the data stored in the SonR histograms can be used to generate an estimate of the SonR augmentation from rest to exercise;

- Observe, qualitatively, whether the changes in the SonR1 augmentation curve can be attributed to other measures of functional exercise capacity or cardiac pathologies;

- Investigate the relationship between SonR1 amplitude, heart rate, respiratory rate/amplitude and activity level during patients* daily activities;

- Observe, qualitatively, any differences in the change of SonR features with heart rate between the ischemic and non-ischemic patients;

- Compare the SonR augmentation calculated from the histogram data and that measured from the raw SonR data;

- Assess the quality of the MV signal recorded using different lead reference, in different filtering conditions;

- Report all the serious adverse events.

Study description

Background summary

Heart failure is a medical condition defined by the inability of the heart to provide sufficient blood flow to meet the metabolic demand of the body. In many cases this is due to a lack of synchronization between the contraction of the left and right ventricles, itself caused by electrical conduction issues such as left bundle branch block (LBBB). Patients with such a condition may be eligible for the implantation of a cardiac resynchronization therapy (CRT) device comprises a stimulator and two or more stimulating electrodes or leads. The leads are implanted via the vasculature and are located in or adjacent to the left and right ventricles and often additionally the right atrium. Therapy is delivered in the form of electrical pulses which cause local depolarization of the cardiac tissue and ultimately the contraction of the heart. Resynchronization is achieved by careful selection of the timing of the pulses which may be set by the implanting physician or, in some cases, derived automatically.

Study objective

The primary objective of the PASSENGER study is to investigate any relationship between changes in SonR1 augmentation and a change in patients* exercise capacity as assessed by the 6 Minute Walk Test.

Study design

European, prospective, single arm multicenter feasibility study

Intervention

During pre-discharge, 6 weeks and 6 month visits patients ave to do a 6 Minute Walk Test. Also during 6 week visit patients have to do an exercise stress test.

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

- patients implanted with a CRT-D device according to published relevant ESC guidelines in the last 5 days;
- patients implanted with an Implantable cardioverter defibrillator (CRT-D) device equipped with SonR technology;
- patients implanted with a SonRtip tm right atrial lead;
- patients in sinus rhythm;
- patients on stable medical therapies regimen;
- patients capable to perform stress test;
- patients reviewed, sign and dated an informed consent form

Exclusion criteria

patients with:
- persistent atrial arrhythmias within the past three months;
- unstable angina or acure MI within the past 3 months;

- already included in another clinical study that could confound the results of this study
- pregnancy;
- vulnerable subjects as defined in ISO 14155:2011;
- unavailability for scheduled follow-up or refusal to cooperate

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	CRT-D device;leads and software
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	06-11-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL48753.028.14