

Microvascular function and psychological factors in heart failure patients treated with cardiac resynchronisation therapy (CRT)

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The aim of the proposed study is to examine whether CRT has a positive effect on microvascular function and health outcomes, and whether psychological factors may moderate the effect of CRT on health outcomes.

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON31791

Source

ToetsingOnline

Brief title

Microvascular function, psychological factors and CRT

Condition

- Heart failures

Synonym

cardiac failure, congestive heart failure

Research involving

Human

Sponsors and support

Primary sponsor: TweeSteden ziekenhuis

Source(s) of monetary or material Support: Medtronic Trading NL BV, wetenschapsfonds ziekenhuis; grants bedrijfleven; bijdrage van de Universiteit van Tilburg

Intervention

Keyword: cardiac resynchronization, heart failure, microcirculation, psychological distress

Outcome measures

Primary outcome

Primary: Microvascular function as measured by blood flow response to endothelium-dependent and endothelium-independent vasoactive stimuli (acetylcholine, nitroprusside, local heating); health status; cardiac symptoms; health care consumption.

Secondary outcome

Secondary: Mortality; morbidity (defined as hospitalisation for cardiac reasons).

The primary endpoint, health care consumption, and the secondary endpoints, mortality and morbidity, will be assessed at T4 (i.e. 14 months post-CRT), with the information being obtained through the patients' medical records.

Study description

Background summary

In chronic heart failure (CHF), the heart is no longer capable of pumping sufficient blood to fulfil the nutritional and oxygen needs of organs and tissues. Also, microvascular function is compromised. A subgroup of CHF patients can be treated with cardiac synchronization therapy (CRT), eventually CRT combined with an Implantable Cardioverter Defibrillator (ICD). However, the effects of CRT on microvascular function are not known. Furthermore, not all patients experience improvements following CRT, and it is important to gain knowledge about clinical and psychological parameters that predict poor health

outcomes in post-CRT patients.

Study objective

The aim of the proposed study is to examine whether CRT has a positive effect on microvascular function and health outcomes, and whether psychological factors may moderate the effect of CRT on health outcomes.

Study design

This is a single-centre observational prospective study.

Study burden and risks

The tests are non-invasive, and painless. Extra visits to the hospital will be reduced to a minimum, because appointments for the proposed study will be scheduled together with standard pacemaker check-ups. For determination of microvascular functioning, vasoactive drugs will be administered transdermally in very low dosages which yield no systemic side-effects. Therefore, there is minimal risk and minimal burden to patients associated with this study.

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

diagnosis of chronic heart failure with a left ventricular ejection fraction of 40% or less

being on optimal medical therapy

NYHA functional class III/IV

QRS duration of ≥ 120 msec

In addition, at least one of the following echocardiographic criteria has to be fulfilled: an aortic pre-ejection delay > 140 msec, an interventricular mechanical delay > 40 msec, or delayed activation of the posterolateral left ventricular wall

Exclusion criteria

Inability to read, write or understand Dutch, a history of psychiatric illness other than mood disorders (depression/anxiety), significant cognitive impairments (e.g. dementia) or life-threatening co morbidities (e.g. cancer).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2008

Enrollment: 55

Type: Anticipated

Ethics review

Approved WMO

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	NL19332.028.07