Effects of Cardiac Resynchronization Therapy on the Microcirculation (CaRe-Mi)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32204

Source
ToetsingOnline

Brief title
Microcirculation during cardiac resynchronization

Condition

- Other condition
- Heart failures

Synonym
chronic heart failure, weak heart

Health condition

alterations of microcirculation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac resynchronization therapy (CRT), microcirculation

Outcome measures

Primary outcome

The main study parameter is the CRT- and acetylcholine-related effects on the microcirculation as expressed as the change in mean functional capillary density during different pacing settings and pharmacologic vasodilatation.

Secondary outcome

Secondary parameters are additional microvascular parameters: red blood cell velocity and microvascular flow index (MFI). Furthermore, the correlation of microcirculatory and systemic hemodynamic parameters will be investigated.

Study description

Background summary

Cardiac resynchronization therapy (CRT) is accepted as an adjunctive therapeutic option for patients with congestive heart failure (CHF) with optimal pharmacologic regimen. It is known that CRT improves the systemic circulation, physical performance, quality of life and outcome. However, not all patients treated do respond to cardiac resynchronization therapy. The reasons for this are not completely understood. Besides various possible ways of pacing the heart, the different responses of the microcirculation to CRT, and therefore different supply of organs with oxygen and nutrients, may account for the varying outcome. In a pilot study, in responders to CRT, improvement of the microcirculation has been found. However, the relation between cardiac and systemic hemodynamics remains to be elucidated.

Study objective

The primary objective of this project is to test the hypothesis that CRT exerts beneficial effects on the microcirculation by recruitment of capillaries. The secondary objective is to compare the microcirculatory with the hemodynamic parameters and the changes in the microcirculation in responders versus non-responders to CRT.

Study design

Single-center, case-control study

Intervention

5 different areas of the sub-lingual microcirculation will be imaged by use of Sidestream Dark Field (SDF) imaging hand microscope. Images will be acquired during: no pacing (if the patient is not pacing dependent), monoventricular pacing, biventricular pacing, and after sublingual application of pharmacological vasodilatation with local acetylcholine. Each pacing set-up will have a pacing rate of 60 per minute and will be maintained for 15 minutes. At each measuring time point heart rate, blood pressure, velocity time integral (VTI) over the aortic valve and cardiac output will be recorded non-invasively. Semi-quantitative posthoc analysis of the recordings of the microcirculation will be performed using the Microvascular Analyzing Software.

Study burden and risks

The patient does not have to change habits, therapy or follow a special diet before or after this study. All measurements performed during the study are painless and non-invasive. The study will last one visit of 1 hour. The patients are asked to fill in a form asking for generalities, cardiovascular risk factors, Canadian Cardiovascular Society (CCS) and NYHA scores and pharmacologic regimen. A 12 lead ECG is performed. The CRT device is programmed transcutaneously. At each programming step non-invasive, painless sublingual imaging of the microcirculation is performed by means of a hand held microscope (SDF) during 5 sets of 5-10 minutes. Pauses in the imaging can be interposed as requested by the patient. At each pacing step the VTI over the aortic valve is measured by transthoracic echocardiography. The local application of acetylcholine (10e-2 M) confers a minimal risk for systemic symptoms.

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

* Older than 18 years
* Chronic heart failure
* CRT device implanted
* Informed consent is given

Exclusion criteria

* Younger than 18 years
* Pacing dependency (no intrinsic rhythm)
* Pre-existing renal failure requiring dialysis
* Known haemoglobin diseases, such as sickle cell anemia or thallasemia
* Known allergy to acetylcholine or its additives
* Missing informed consent
* Inability to walk

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	51
Type:	Anticipated

Medical products/devices used

Generic name:	acetylcholine
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22793.018.08