The effect of left ventricular filling pressure on pulmonary clearance of free radical loaded white blood cells and platelets in congestive heart failure patients before and after biventricular pacing

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1) To assess whether a correlation exist between the degree of pulmonary clearance of free radical positive white bloodcells and platelets and the degree of pulmonary congestion in congestive heart failure (CHF) patients2) To asses whether cardiac...

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

Summary

ID

NL-OMON31660

Source
ToetsingOnline

Brief title
OXIS-PACING

Condition

- Heart failures

Synonym
Decompensatio Cordis, Heart failure

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Oxidative stress, Platelets, Resynchronization, White blood cells

Outcome measures

Primary outcome

·Oxidative stress: cytosolic and mitochondrial FR

Bloodsamples are incubated with a fluorescent CM-DCF probe, which detects

cytosolic FR, or with a Mito-FR probe, which detects mitochondrial FR.

WBCs and platelets with significant fluorescence are identified by FACS and

reported relative to their total number.

·Number of (apoptotic) endothelial (progenitor) cells

LV filling pressure determined by invasive measurement at the time of

biventricular pacemaker implantation

Secondary outcome

see figure 2 en pag. 16 protocol

Study description

Background summary

Evidence exists that oxidative stress is enhanced in congestive heart failure patients resulting in damage to cellular lipids, proteins and DNA. Because of free radical-induced apoptosis of skeletal muscle fibers, oxidative stress is an important contributor to skeletal muscle fatigue and low exercise tolerance of congestive heart failure patients. Enhanced oxidative stress in

congestive heart failure can exert negative inotropic effects and can have important effects on the structure and function of the myocardium, and may be implicated in the progression of congestive heart failure. Free radical stress could also impair recruitment and differentiation of circulating endothelial progenitor cells resulting in increased all cause mortality.
Reduced pulmonary clearance of free radical loaded white blood cells and platelets is an important contributor to enhanced oxidative stress in congestive heart failure patients. Failure of pulmonary clearance of free radical loaded white blood cells and platelets probably results from pulmonary congestion which has led to the rationale of the current study. Biventricular pacing for resynchronization therapy in congestive heart failure patients reduces left ventricular filling pressure and pulmonary congestion. Biventricular pacing may therefore augment pulmonary clearance of free radical loaded white blood cells and platelets in congestive heart failure patients.
We conduct a prospective, observational clinical study to investigate the correlation of left ventricular filling pressure, pulmonary clearance of FR loaded circulating white blood cells and platelets and number of endothelial progenitor cells in congestive heart failure (CHF) patients before and after implantation of a biventricular pacemaker for resynchronization therapy.

Study objective

1) To assess whether a correlation exist between the degree of pulmonary clearance of free radical positive white bloodcells and platelets and the degree of pulmonary congestion in congestive heart failure (CHF) patients
2) To asses whether cardiac resynchronization therapy improves pulmonary clearance of free radical positive white blood cells and platelets in CHF patients by alleviating pulmonary congestion
3) Interaction of oxidative stress with circulating endothelial progenitor cells (EPCs) and presence of apoptotic endothelial (progenitor) cells

Study design

See protocol

Study burden and risks

Time investiment for the patient (1/2 a day for follow up)
Very small risk for heamatoma after blood withdrawel.

Met name tijdsbelasting voor patient (1/2 dag terugkomen voor follow-up).
Zeer kleine kans op de vorming van een hematoom a.g.v. bloedafname tijdens follow-up.

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 congestive heart failure patients of all ages selected for biventricular pacemaker implantation for resynchronization therapy
·Dyspnoe NYHA class III and IV
·Optimal and constant heart failure treatment according to the ESC guidelines

Exclusion criteria

·Renal failure (creatinine >1.70 mg/dl)
·Signs of infection or inflammation

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2008
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
ClinicalTrials.gov	NCT00716885
CCMO	NL21219.067.08