The Influence of Psychological Factors on Health Outcomes in Patients Treated with Cardiac Resynchronization Therapy: A Prospective, Single-Center, Observational Study.

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Primary1. To examine whether psychological factors moderate the effect of the objectively assessed clinical CRT-D response on quality of life in patients with CHF.Secondary2. To examine whether psychological factors moderate the effect of the...

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

Summary

ID

NL-OMON35428

Source
ToetsingOnline

Brief title
Psychological outcome in Cardiac Resynchronization Therapy.

Condition

- Heart failures

Synonym
chronic heart failure, reduced cardiac output

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biomarker, cardiovascular, health outcome, psychological

Outcome measures

Primary outcome

(1) Health status/quality of life

Secondary outcome

(2) Mortality (both cardiac and non-cardiac)

(3) Morbidity

Study description

Background summary

Cardiac resynchronization therapy with defibrillator (CRT-D) is a promising treatment in congestive heart failure (CHF), both in terms of improving functional status and quality of life and in reducing mortality and morbidity. However, despite proven benefits, a subgroup of patients (20-30%) still report impaired quality of life and functional status following CRT, which cannot be explained solely by traditional objective indicators of CHF severity. A paucity of studies have examined the role of psychological factors in predicting health outcomes, such as quality of life and morbidity, in patients treated with CRT-D. In addition, little is known about the relationship between psychological factors and cytokine activation in heart failure.

Study objective

Primary
1. To examine whether psychological factors moderate the effect of the objectively assessed clinical CRT-D response on quality of life in patients with CHF.

Secondary

2. To examine whether psychological factors moderate the effect of the objectively assessed clinical CRT-D response on morbidity in patients with CHF.
3. To investigate whether the relationship between Type D personality and 2-year mortality and morbidity in CHF patients treated with CRT-D is mediated by cytokine activation.

Study design

Prospective, observational, single-centre study, with a 2-year follow-up. Psychological assessments will take place at 5 time points during a period of 12 months. At visits to the outpatient clinic, patients will undergo standard medical tests, give blood for the determination of cytokine activation, and complete a set of standardized and validated questionnaires. Information on medical characteristics and adverse clinical events during the 2-year follow-up period will be retrieved from the patients* medical records.

Study burden and risks

The proposed study incurs no extra risk to patients, as they receive no additional treatment and/or tests nor will any treatment be withheld from them compared to patients who choose not to participate or are excluded on the basis of the exclusion criteria. No extra venapuncture will take place, as the extra blood samples for the study will be taken at the time of the standard assessments for the clinical management of patients. The only burden to patients is the time that it will take to complete a set of psychological questionnaires at the clinical follow-up visits, which is estimated to take 1 hour. Given that patients often have to wait for the different tests and appointments with various professionals at the outpatient clinic, the questionnaires can be completed during this waiting period.

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 aged between 18-85 years and receiving a CRT-D device, according to the most recent guidelines.

Exclusion criteria

Patients with a history of psychiatric illness other than affective/anxiety disorders, with cognitive impairments (e.g. dementia), being treated with anti-inflammatory drugs other than low-dose aspirin, on dialysis or a creatinine level > 250 micromol/liter, with chronic systemic disease and treated with corticosteroids, chemotherapy, or colchicines, on the waiting list for heart transplantation, or with insufficient knowledge of the Dutch language will be excluded.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2009
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-11-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL21600.041.08