Resynchronization/defibrillation for Ambulatory Heart Failure Trial (RAFT)

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The RAFT study addresses the added value of resynchronization therapy (CRT) in heart failure patients with an ICD indication and optimal pharmacological treatment. Will this result in lower mortality and less hospitalization? Results of the study…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON31905

Source
ToetsingOnline

Brief title
RAFT

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: defibrillation, heart failure, resynchronisation

Outcome measures

Primary outcome

The primary outcome is a composite of total mortality and heart failure hospitalization.

Secondary outcome

Secondary outcome measures include total mortality, cardiovascular mortality, sudden arrhythmic death, hospitalization, health related quality of life, and health economics. Other outcome measures: 6 minute hall walk distance, NYHA Class changes, development of new atrial fibrillation, and non-fatal ventricular tachycardia.

Study description

Background summary

Cardiac Resynchronization Therapy (CRT) is proven to be effective in patients with advanced and severely debilitating heart failure (NYHA class III and IV). The RAFT trial examines the added value of CRT to ICD and medical therapy in patients with less advanced heart failure (NYHA class II).

Study objective

The RAFT study addresses the added value of resynchronization therapy (CRT) in heart failure patients with an ICD indication and optimal pharmacological treatment. Will this result in lower mortality and less hospitalization?
Results of the study may improve the treatment of these heart failure patients (NYHA class II).

Study design

RAFT is a multi-center, prospective, double-blinded, randomized, controlled

trial. A total of 1800 heart failure patients with an implantable cardioverter Defibrillator (ICD) indication will be included in 21 centers. Patients will be randomly assigned (1:1 ratio) to one of two treatment groups: 1) ICD with CRT (experimental group) and 2) ICD without CRT (control group). Both groups will receive optimal pharmacological treatment.

Patients will be followed until the last enrolled patient completes the 18 month follow-up visit. Patients are followed during hospital follow-up visits at 1, 6 and 12 months and, thereafter, every 6 months by blinded study personnel who perform a heart failure assessment, and by unblinded study personnel who perform the device follow-up. Additionally, in between hospital visits, a blinded heart failure assessment and check for hospitalizations is performed over the phone (3, 9 and 15 months post implant).

Intervention

ICD without CRT (control group) versus ICD plus CRT (experimental group). Both groups receive optimal pharmacological treatment.

Study burden and risks

Burden/risk: Patients in the experimental group (ICD with CRT) will receive an extra lead for stimulation of the left ventricle. This procedure involves standard risks (p.3 patient information).
Benefit: Participating patients will be under more extensive medical surveillance. The study may result in an improved treatment for patients with less advanced heart failure.

Contacts

Public
Medtronic

Postbus 2542
6401 DA Heerlen
Nederland
Scientific
Medtronic

Postbus 2542
6401 DA Heerlen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(Protocol p.10)
• NYHA Class II
• LV EF <= 30%
• Intrinsic QRS Complex Width >= 120 ms OR Paced QRS measurement >= 200 ms
• ICD indication for primary or secondary prevention (single or dual chamber system)
• Optimal heart failure pharmacological therapy
• Normal Sinus Rhythm OR
- Chronic persistent Atrial Tachyarrhythmia with resting Ventricular Heart Rate <= 60 bpm and 6 Minute Hall Walk Ventricular Heart Rate of <= 90 bpm OR
- Chronic persistent Atrial Tachyarrhythmia with resting Ventricular Heart Rate > 60 bpm and 6 Minute Hall Walk Ventricular Heart Rate of > 90 bpm and booked for Atrio-Ventricular Junction Ablation

Exclusion criteria

(Protocol p.10-11)
• Intra-venous inotropic agent in the last 4 days
• Patients with a life expectancy of less than one year from non-cardiac cause
• Expected to undergo cardiac transplantation within one year (status I)
• Patients with an acute coronary syndrome including MI1 can be included if the patient has had a previous MI with LV dysfunction (LVEF <= 30%)
• In hospital patients who have acute cardiac or non-cardiac illness that requires intensive care
• Uncorrected or uncorrectable primary valvular disease
• Restrictive, hypertrophic or reversible form of cardiomyopathy
• Severe primary pulmonary disease such as cor pulmonale
• Tricuspid prosthetic valve

• Patients with an existing ICD (Patients with an existing pacemaker may be included if the patients satisfies all other inclusion/exclusion criteria)
• Coronary revascularization (CABG3 or PCI4) < 1 month if previously determined LVEF > 30%
Patients with a more recent revascularization can be included if a previous determined LVEF was <= 30%
• Patients included in other clinical trial that will affect the objectives of this study
• History of noncompliance of medical therapy
• Unable or unwilling to provide informed consent

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2008
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	ICD;CRT
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-01-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NCT00251251
CCMO	NL19769.075.07