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Resynchronisation/defibrillation for Ambulatory heart Failure Trial

Submission date 18/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/11/2005	**Overall study status** Completed	
Last Edited 03/09/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00251251

Protocol serial number
UCT-63208

Study information

Scientific Title

The addition of cardiac resynchronisation therapy to implantable cardioverter-defibrillator and optimal medical therapy to patients with mild to moderate congestive heart failure symptoms: a randomised controlled trial

Acronym
RAFT

Study objectives
In patients with left ventricular (LV) dysfunction (ejection fraction [EF] less than or equal to 30%), QRS duration greater than or equal to 120 ms, and mild to moderate congestive heart failure (CHF) symptoms, the addition of cardiac resynchronisation therapy (CRT) to implantable cardioverter-defibrillator (ICD) and optimal medical therapy reduces the combined end point of all-cause mortality and CHF hospitalisation.

As of 06/03/2009 this record was updated; all amendments can be found in the relevant field under the above update date. Please note that the countries of recruitment were extended at this time to include Germany, Australia, Belgium, Netherlands and Turkey. At this time the anticipated end date was also amended; the initial end date at the time of registration was 30/04 /2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Board, University of Ottawa Heart Institute, Ottawa Ontario approved on the 27/11/2002

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Congestive heart failure

Interventions
ICD plus Optimal Medical Therapy (control) or CRT/ICD plus Optimal Medical Therapy (experimental); permanent implanted device-length of study

Trial details received 12 Sept 2005

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Total mortality and hospitalisation for CHF. Total mortality includes any death. Hospitalisation for CHF is defined as an admission to hospital with a diagnosis of worsening CHF for greater than 24 hours.

Key secondary outcome(s)
1. Cardiovascular mortality in comparison to total mortality same as above
2. Sudden arrhythmic death in comparison to total mortality as above
3. Progressive CHF death in comparison to total mortality same as above
4. All causes of hospitalisation rate
5. CHF hospitalisation rate throughout the length of the trial
6. Health related quality of life and cost economics using the MLWHF questionnaire and EQ5D questionnaire

Completion date
31/08/2010

Eligibility

Key inclusion criteria
Amended 06/03/2009:
Point 2 has been removed: 'Aged greater than or equal to 30, either sex'.

Initial information at the time of registration:
1. New York Heart Association (NYHA) class II
2. Aged greater than or equal to 30 years old, either sex
3. LVEF less than or equal to 30% by multiple gated acquisition (MUGA) scan or LVEF less than or equal to 30% and LV end diastolic dimension greater than 60 mm (by echocardiogram) within 6 months of randomisation
4. QRS duration greater than or equal to 120 ms
5. Optimal heart failure pharmacological therapy
6. ICD indication for primary or secondary prevention
7. Normal sinus rhythm OR chronic persistent atrial fibrillation with resting ventricular heart rate less than or equal to 60 bpm and ventricular rate less than or equal to 90 bpm during a 6-minute hall walk. This can be accomplished by pharmacological therapy or catheter AV Junction Ablation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. In hospital patients who have acute cardiac or non-cardiac cause
2. Intra-venous inotropic agent in the last 4 days
3. Patients with a life expectancy of less than 1 year non-cardiac cause
4. Expected to under go cardiac transplantation within 1 year (status I)
5. Patients with an acute coronary syndrome including myocardial infarction (MI) can be included if the patient has had a previous MI with LV dysfunction (LVEF less than or equal to 30%)
6. Unable or unwilling to provide informed consent
7. History of noncompliance of medical therapy
8. Uncorrected or uncorrectable primary valvular disease
9. Restrictive, hypertrophic or reversible form of cardiomyopathy
10. Severe primary pulmonary disease such as cor pulmonale
11. Tricuspid prosthetic valve
12. Patients included in other clinical trial that will affect the objectives of this study
13. Coronary revascularisation (coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI]) less than 1 month if previously determined LVEF greater than 30%. Patients with a more recent revascularisation can be included if a previous determined LVEF was less than or equal to 30%
14. Patients with an existing ICD (patients with an existing pacemaker may be included if the patients satisfies all other inclusion/exclusion criteria)

Date of first enrolment
01/04/2003

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
Australia

Belgium

Canada

Germany

Netherlands

Türkiye

Study participating centre
University of Ottawa Heart Institute
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Sponsor information

Organisation
University of Ottawa Heart Institute (Canada)

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-63208)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Protocol article	protocol	01/01/2009		Yes	No