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Atrial fibrillation and congestive heart failure (AF-CHF) study

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2014	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00597077

Secondary identifying numbers
MCT-41552

Study information

Scientific Title
Restoring and maintaining sinus rhythm versus rate control treatment strategy to reduce cardiovascular mortality in patients with atrial fibrillation and congestive heart failure: a randomised controlled trial

Acronym
AF-CHF

Study objectives
Restoring and maintaining sinus rhythm reduces cardiovascular mortality (instead of 'improves survival') compared to a rate control treatment strategy in patients with AF and CHF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité d'éthique de la recherche et du développement des nouvelles technologies, Institut de Cardiologie de Montréal, 05/04/2001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation, congestive heart failure

Interventions
1. Restoring and maintaining sinus rhythm compared to a rate control treatment strategy
2. Resting electrocardiogram (ECG) and a 6-minute walk test
3. Electrical cardioversion
4. Pacemaker implantation

Trial details received: 12 Sept 2005

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Cardiovascular death during follow-up which will end for all patients on 30/06/2007

Secondary outcome measures
1. Total mortality
2. Stroke
3. Hospitalisation
4. Quality of life
5. Cost of therapy
6. Composite endpoint of cardiovascular death and stroke

Overall study start date
01/10/2000

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Symptomatic CHF (New York Heart Association [NYHA] class II - IV) at some time during the 6 months before randomisation (instead of '3 months')
2. Aged greater than or equal to 50 years old, either sex
3. Left ventricular ejection fraction less than or equal to 35%
4. History of significant atrial fibrillation
5. Patients must be eligible for long term treatment with either treatment strategy of AF
6. AF is known to be present and uninterrupted for greater than 12 months prior to randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1375

Key exclusion criteria
1. Reverse cause of AF such as acute pericarditis, pulmonary embolism, hyperthyroidism, alcohol intoxication
2. Unstable (pulmonary oedema, hypoperfusion) decompensated CHF

3. Antiarrhythmic drugs other than calcium channel blockers, beta-blockers or digoxin required for other arrhythmias or indications
4. Atrial fibrillation occurring and not persisting beyond 10 days after surgery or myocardial infarction
5. Second or third degree AV block, sinus pause greater than 3 seconds, resting heart rate less than 50 bpm without a permanent pacemaker
6. History of drug-induced or congenital long QT syndrome
7. Reversible causes of CHF such as severe aortic or mitral stenosis and tachycardia-induced cardiomyopathy
8. Prior AV nodal ablation or maze surgery
9. Probable cardiac transplantation in the next 6 months
10. Chronic renal failure requiring dialysis
11. Women of childbearing potential and not on a reliable method of birth control

Date of first enrolment
01/10/2000

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Canada

Israel

United States of America

Study participating centre
Montreal Heart Institute
Montreal
Canada
H1T 1C8

Sponsor information

Organisation
Montreal Heart Institute (Canada)

Sponsor details
5000 est, rue Bélanger
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Sponsor type
Research organisation

Website
http://www.icm-mhi.org

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-41552)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/10/2002		Yes	No
Results article	results	19/06/2008		Yes	No
Results article	results	01/02/2014		Yes	No