

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Denis Roy

Contact details
Montreal Heart Institute
5000 Belanger Street East
Montreal
Canada
H1T 1C8
+1 514 376 3330 ext. 3652
d_roy@icm-mhi.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00597077

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Total mortality
2. Stroke
3. Hospitalisation

4. Quality of life
5. Cost of therapy
6. Composite endpoint of cardiovascular death and stroke

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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