

Effect of targeting left ventricular lead position on the rate of response to resynchronisation therapy in patients with Coronary Artery Disease

Submission date 17/06/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/02/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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)
NCT00399594

Protocol serial number
MCT-87465

Study information

Scientific Title

Investigating Non-response to Cardiac Resynchronisation: Evaluation of Methods to Eliminate Non-response and Target Appropriate Lead location in patients with Coronary Artery Disease

Acronym

INCREMENTAL-CAD

Study objectives

Primary hypothesis:

Echo-guided left ventricular (LV) lead placement will result in an increased probability of cardiac resynchronisation therapy (CRT) response at 9 months versus usual (postero-lateral/lateral wall) lead placement.

Secondary aims:

Assess the utility of the following baseline variables to predict CRT response:

1. Greater than or equal to 15% myocardial scarring on cardiac magnetic resonance imaging (MRI)
2. Greater than or equal to four viable segments on dobutamine echo
3. N-terminal B-type natriuretic peptide levels

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Board of University approved of Calgary on the 18th November 2004 (ref: 18058).

Study design

Interventional, double blind (participant, caregiver, outcomes assessor) randomised parallel assignment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

Experimental intervention:

Targeted LV lead placement based on results of echo imaging.

Control intervention:

Usual LV lead placement.

The duration of each intervention/follow-up in 9 months in both groups.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

CRT response (greater than or equal to 10% relative reduction in left ventricular end systolic volume and greater than or equal to one Specific Activity Scale class reduction) at 9 months.

Key secondary outcome(s)

1. Clinical events (mortality and hospitalisation) from implant until 9 months
2. Safety (procedural time, contrast use, fluoroscopy time, procedural complications - minor and severe) from implant until 9 months
3. Pacing efficacy (pacing thresholds) from implant until 9 months

Completion date

30/03/2012

Eligibility**Key inclusion criteria**

1. Left ventricular ejection fraction (LVEF) less than or equal to 0.35 measured within three months of enrolment
2. Specific Activity Scale (SAS) class 3 or 4 symptoms (moderate to severe functional capacity limitation due to heart failure) within 1 month of enrolment
3. QRS width greater than 120 ms
4. Confirmed dyssynchrony on screening echo
5. Documented history of ischaemic heart disease (prior myocardial infarction, prior coronary artery bypass, prior coronary angioplasty, or imaging confirmation [angiogram, cardiac MRI])
6. On stable doses of angiotensin converting enzyme (ACE) inhibitor or angiotensin II blocker and a beta-blocker for greater than or equal to two months unless medically contra-indicated
7. Controlled heart rate if in permanent atrial fibrillation (AF) (resting rate less than 70 and maximal rate less than 120 bpm)
8. Patients aged 18 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Unable or unwilling to provide informed consent
2. Medical condition other than heart failure likely to cause death within 12 months
3. Cardiac transplant planned within six months
4. Known contra-indication to transvenous CRT device implant (e.g., active sepsis, artificial tricuspid valve, known vascular occlusion that will prevent delivery of transvenous leads)
5. Clinically significant myocardial infarction within last two months
6. Coronary artery bypass graft surgery less than or equal to two months or coronary angioplasty less than or equal to one month

Date of first enrolment

01/09/2008

Date of final enrolment

30/03/2012

Locations

Countries of recruitment

Canada

Study participating centre

G208, 3330 Hospital Drive NW

Calgary, Alberta

Canada

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Sponsor information

Organisation

University of Calgary (Canada)

ROR

<https://ror.org/03yjb2x39>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-87465)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration