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	[X] Prospectively registered [_] Protocol
Registration date 17/06/2008	Overall study status Completed	 Statistical analysis plan Results
Last Edited 19/02/2019	Condition category Circulatory System	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name Dr Derek V Exner

Contact details

G208, 3330 Hospital Drive NW Health Sciences Centre University of Calgary Calgary, Alberta Canada T2N 4N1 +1 403 220 3219 exner@ucalgary.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00399594

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/09/2008

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

Age group

Adult

Lower age limit

18 Years

Sex Both

Target number of participants 300

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 T2N 4N1

Sponsor information

Organisation University of Calgary (Canada)

Sponsor details 2500 University Drive N.W. Calgary, Alberta Canada T2N 1N4

Sponsor type University/education

Website http://www.ucalgary.ca/

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

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