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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
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

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