ISRCTN42560370 https://doi.org/10.1186/ISRCTN42560370

Evaluation of resynchronization therapy for heart failure (EARTH)

Submission date	Recruitment status	[ ] Prospectively registered
09/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/09/2005	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/02/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Bernard Thibault

Contact details
Montreal Heart Institute
5000 Belanger Street East
Montreal
Canada
H1T 1C8
+1 514 376 3330 ext. 3776
earth-study.icm@icm-mhi.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00900549

Secondary identifying numbers
UCT-67914

Study information

Scientific Title
Evaluation of resynchronization therapy for heart failure (EARTH)

Acronym
EARTH

Study objectives
The primary hypothesis of the LESSER-EARTH is that heart failure patients with an indication for an implantable cardioverter defibrillator (ICD) without a prolonged QRS duration will benefit clinically from resynchronization therapy.

The primary hypothesis of the GREATER-EARTH is that heart failure patients with an indication for an ICD and for cardiac resynchronisation therapy (CRT) will benefit better clinically with left ventricular (LV)-based CRT than with biventricular (BiV)-based CRT.

As of 01/06/2009 and 05/06/2009 this record was updated. All updates can be found under the relevant field with the above update dates. At this time, the trial dates were updated; the initial trial dates at the time of registration were:
Initial anticipated start date: 01/01/2005
Initial anticipated end date: 31/12/2005

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Comité d'éthique de la recherche et du développement des nouvelles technologies de l'Institut de Cardiologie de Montréal) approved on the 11th November 2003.

Study design
Randomized 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
Heart failure

Interventions
1. Insertion of the resynchronization pacing system
2. Control tests to ensure condition is stable and device functioning properly
3a. Lesser-Earth: patients randomized to resynchronization on versus off. 12-month follow-up.
3b. Greater-Earth: patients randomized to LV resynchronization verus BiV resynchronization. Cross-over 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Total exercise duration at constant sub-maximal load (defined as 75% of peak exercise during the baseline metabolic evaluation).

Secondary outcome measures
1. Clinical endpoints (Quality of Life [QoL], New York Heart Association [NYHA])
2. Electrical endpoints (ECG)
3. Echocardiographic endpoints (LVEF and volumes)
4. MUGA scan endpoints (LVEF and synchrony index)
5. Neuro-hormones (brain natriuretic peptide [BNP], atrial natriuretic peptide [ANP])

Overall study start date
01/11/2003

Completion date
01/03/2010

Eligibility

Key inclusion criteria
Correct and updated information as of 05/06/2009:
Patient must answer "yes" to the following questions:
1. Does the patient require an ICD or an ICD replacement?
2. Does the patient have a documented left ventricular ejection fraction (LVEF) less than or equal to 35% measured in the previous 6 months (without major concomitant clinical event)?
3. Does the patient have a QRS duration of less than 120 ms?
4. Is the patient in sinus rhythm?
5. Was the six-minute walk test distance less than 400 meters and limited by heart failure symptoms?

Initial (incorrect) information at time of registration:
1. Diagnosis of asthma verified by primary care MD.
2. Aged greater than or equal to 18 years old, either sex
3. Asthma managed by primary care MD and receiving asthma drug therapy from primary care MD

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
Amended as of 05/06/2009:
Point one of the below exclusion criteria has been amended as follows:
1. Indication for permanent pacing or with chronotropic insufficiency defined as follows:
1.1. Any condition where the treating physician believes it would not be acceptable for the patient to have his device NOT programmed with the SENSOR at ON
1.2. Second or third degree AV block, either persistent or intermittent block
1.3. Patients with a pacemaker or an ICD who are paced in either chamber (A or V) more than 5% of the time

Initial information at time of registration:
1. Indication for permanent pacing or with chronotropic insufficiency defined as follows:
1.1. Severe sinus bradycardia (resting heart rate less than 50/min)
1.2. Chronotropic insufficiency, defined as a heart rate during the screening 6-minute walk test that does not increase by more than 10 beats/minute compared to the resting rate
1.3. First degree AV block with a PR interval greater than 250 ms, Second or third degree AV block, either persistent or intermittent
1.4. Patients with a pacemaker or an ICD who are paced in either chamber (A or V) more than 5% of theme
2. LV dysfunction associated with a reversible cause such as post-partum cardiomyopathy, tachycardia induced cardiomyopathy, acute myocarditis or acute toxic cardiomyopathy (including acute alcoholic)
3. Myocardial infarction within the past 6 weeks (defined by two of the three following conditions: prolonged chest pain, electrocardiogram (ECG) changes suggesting of acute myocardial infarction (AMI) or cardiac enzymes elevation more than twice the local upper limit of normal)
4. Cardiac surgery within the past 6 weeks
5. Coronary angioplasty within the past 6 months
6. Moderate or severe cardiac valve stenosis
7. Inability or a limitation to walk for reasons other than heart failure symptoms (e.g. angina, intermittent claudication, severe lung condition or arthrosis)
8. Severe coexisting illnesses making survival greater than 6 months unlikely
9. Pregnancy and/or nursing
10. Inability or unwillingness to consent or comply with follow-up requirements
11. Participation in another study

Date of first enrolment

01/11/2003

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute
Montreal
Canada
H1T 1C8

Sponsor information

Organisation
Montréal Heart Institute (Canada)

Sponsor details
5000 est, rue Bélanger
Montréal
Canada
H1T 1C8
+1 514 376 3330
earth-study.icm@icm-mhi.org

Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

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: UCT-67914)

Funder Name
St. Jude Medical Canada Inc. (Mississauga, Ont) (Canada)

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