

Evaluation of resynchronization therapy for heart failure (EARTH)

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/09/2005	Overall study status Stopped	<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)
NCT00900549

Protocol serial number
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

Study type(s)

Treatment

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 versus BiV resynchronization. Cross-over 6 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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])

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 them
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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration