

# Evaluation of resynchronization therapy for heart failure (EARTH)

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/02/2019	<b>Condition category</b> 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

**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 versus 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 the time
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