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# Statin Induced Regression of Cardiomyopathy Trial

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|---|---|---|
| **Submission date**<br>17/05/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>21/08/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/02/2019 | **Condition category**<br>Circulatory System | |

**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)**
NCT00317967

**Protocol serial number**
001

## Study information

## Scientific Title
Statin Induced Regression of Cardiomyopathy Trial

## Acronym
Sir Cat

## Study objectives
Treatment with atorvastatin will reduce left ventricular mass and left ventricular focal fibrosis volume, leading to decreased left ventricular wall thickness, decreased left ventricular outflow tract obstruction, improvement in symptoms, decreased propensity to ventricular arrhythmia, and improvement in myocardial relaxation.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Conjoint Health Research Ethics Board, 24/08/2006, ref: 20044

## Study design
Proof of concept, prospective, parallel design, placebo-controlled, multi-center, randomized clinical trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Hypertrophic cardiomyopathy.

## Interventions
Oral administration of atorvastatin vs placebo 80 mg once daily for 12 months.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Atorvastatin

## Primary outcome(s)
Change in left ventricular mass at 12 months from baseline, assessed by 3-dimensional cardiac magnetic resonance imaging at baseline, 6 and 12 months.

## Key secondary outcome(s))
1. Decrease in the incidence of NonSustained Ventricular Tachycardia (NSVT defined as greater than or equal to three consecutive ventricular extrasystoles at greater than or equal to 120

beats per minute), assessed by Holter monitor at baseline, 6 and 12 months
2. Decrease in T wave alternans, assessed by T wave alternans testing at baseline and 12 months
3. Decrease in maximal ventricular wall cross-sectional width
4. Decrease in the volume of dense myocardial fibrosis (absolute fibrotic mass and percentage) as quantified through cardiac magnetic resonance imaging at baseline, 6 and 12 months
5. Laboratory work: creatinine kinase, Creatine Kinase - Myocardial Bands (CKMB), ASpartate aminoTransferase (AST) and ALanine aminoTransferase (ALT) at baseline, 6 and 12 months
6. Quality of Life questionnaire at baseline, 6 and 12 months

### Completion date
31/12/2010

## Eligibility

### Key inclusion criteria
1. 18 years of age and over
2. Hypertrophic cardiomyopathy based on the 2-dimensional echocardiography identification of hypertrophied, nondilated left ventricle (wall thickness with septal-to-posterior wall thickness ratio of 1.3:1) in the absence of another cardiac or systematic disease capable of producing this magnitude of wall thickening
3. Patients may be enrolled > 6 months following either a myectomy or a septal ablation procedure
4. Negative pregnancy test at baseline if female of childbearing potential

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Use of statin therapy or have statin intolerance
2. Clinical diagnosis of hypertension i.e. untreated blood pressure >140/90 on two occasions when measured supine after five minutes at rest
3. Less than six months following either a myectomy or a septal ablation procedure
5. Indication for statin therapy for primary or secondary prevention of coronary artery disease
6. Current or anticipated indication in =< 1 year for implantable cardioverter defibrillators or other metallic devices preventing cardiac Magnetic Resonance Imaging (MRI)

### Date of first enrolment
01/05/2007

**Date of final enrolment**
31/12/2010

# Locations

**Countries of recruitment**
Canada

**Study participating centre**
**University of Calgary**
Calgary
Canada
T2N 4N1

# Sponsor information

**Organisation**
University of Calgary (Canada)

**ROR**
https://ror.org/03yjb2x39

# Funder(s)

**Funder type**
Charity

**Funder Name**
Heart and Stroke Foundation of Alberta, NWT and Nunavut (Canada)

**Funder Name**
Pfizer Cardiovascular Research Award (Canada)

**Funder Name**
Pfizer Canada Inc. donation in kind of study drug (Canada)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2016 | 14/02/2019 | Yes | No |