

Statin Induced Regression of Cardiomyopathy Trial

Submission date 17/05/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/02/2019	Condition category Circulatory System	☐ Individual participant data

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

Primary study design

Interventional

Study design

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

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 $\leq$ 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