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Statin Induced Regression of Cardiomyopathy Trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00317967

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Change in left ventricular mass at 12 months from baseline, assessed by 3-dimensional cardiac magnetic resonance imaging at baseline, 6 and 12 months.

Secondary outcome measures
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

Overall study start date
01/05/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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)

Sponsor details
University of Calgary
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Sponsor type
University/education

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

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

Study outputs

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