ISRCTN32424163 https://doi.org/10.1186/ISRCTN32424163

Effect of cholesterol lowering on progression of aortic stenosis in patients with mild to moderate aortic stenosis

Submission date 05/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/09/2005	**Overall study status** Completed	
Last Edited 06/01/2010	**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

Protocol serial number
DCT-42878

Study information

Scientific Title
Effect of cholesterol lowering on progression of aortic stenosis in patients with mild to moderate aortic stenosis: a randomised controlled trial

Acronym
ASTRONOMER

Study objectives
Primary hypothesis is that patients taking a statin will experience a smaller increase in aortic transvalvular gradients and a smaller decrease in aortic valve area than patients taking placebo over a three-year follow-up period.

Secondary hypotheses are that:
1. The event rate (cardiac death and aortic valve replacement) at the end of three years will be lower
2. The time to outcome events is longer in patients taking a statin than in patients taking placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ottawa Heart Institute Ethics Committee gave approval on the 3rd October 2002.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aortic stenosis (AS)

Interventions
Rosuvastatin 40 mg daily versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rosuvastatin

Primary outcome(s)
Changes in peak transvalvular aortic velocity, transvalvular gradients and aortic valve area

Key secondary outcome(s)
1. Cardiac death measured at the end of three years of follow-up
2. Aortic valve replacement

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Age 18 to 82 years
2. Both men and women will be included
3. At least mild AS defined by peak Doppler aortic valve velocity = 2.5 m/sec
4. Moderate risk for coronary artery disease (CAD), with low density lipoprotein cholesterol (LDL-C) less than 4 mmol/l and total cholesterol: high density lipoprotein cholesterol (HDL-C) ratio less than 6
5. Low risk for CAD with LDL-C less than 5 mmol/l and total cholesterol: HDL-C less than 7

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Peak Doppler aortic valve velocity less than 2.5 m/sec, because of the rate of progression in these patients is not well defined
2. Severe AS (a mean aortic gradient = 40 mmHg or AVA = 0.9 cm^2). These patients are excluded because they will have a high probability of aortic valve replacement even without further AS progression.
3. Symptomatic AS
4. Greater than moderate aortic regurgitation
5. Patients with significant concomitant mitral valve disease, defined by greater than moderate MR or MVA less than 2.0 cm^2
6. Patients on cholesterol lowering agents
7. Symptomatic coronary artery disease
8. Diabetes mellitus either on oral agent or insulin
9. At high or very high risks for CAD (10 year risk greater than 20%)
10. Moderate risk for CAD, but LDL-C greater than 4 mmol/l or total cholesterol: HDL-C ratio greater than 6
11. Low risk for CAD, but LDL-C greater than 5 mmol/l or total cholesterol: HDL-C ratio greater

than 7
12. Pregnant or lactating women
13. Inability to return for follow up visits
14. Concomitant medical conditions, which limit the survival in the next 5 years
15. Inability or unwillingness to provide informed consent

Date of first enrolment
01/12/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Canada

Study participating centre
Dr. K. L. Chan & Adult Congenital Heart Clinic
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Sponsor information

Organisation
University of Ottawa (Canada)

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: DCT-42878)

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	19/01/2010		Yes	No
Other publications	trial design	01/06/2007		Yes	No