

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

<b>Submission date</b> 05/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

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.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Changes in peak transvalvular aortic velocity, transvalvular gradients and aortic valve area

**Secondary outcome measures**

1. Cardiac death measured at the end of three years of follow-up
2. Aortic valve replacement

**Overall study start date**

01/12/2002

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

264

**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<sup>2</sup>). 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<sup>2</sup>
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

Ottawa

Canada

K1Y 4W7

## Sponsor information

**Organisation**

University of Ottawa (Canada)

**Sponsor details**

451 Smyth Road  
P.O. Box 450  
Station A  
Ottawa  
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K1N 6N5

**Sponsor type**

Not defined

**Website**

<http://www.uottawa.ca/>

**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

**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?
<a href="#">Other publications</a>	trial design	01/06/2007		Yes	No
<a href="#">Results article</a>	results	19/01/2010		Yes	No