

# Prospective Randomized Trial of the Effects of Rosuvastatin on the Progression of Stenosis in Adult Patients with Congenital Aortic Stenosis

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/08/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

N/A

## Study information

### Scientific Title

### Acronym

PROCAS

### Study objectives

The primary objective of this study is to determine whether treatment with statins reduce the progression of aortic stenosis in young adult patients with congenital aortic stenosis.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Aortic valve stenosis, congenital heart defects

### Interventions

After completion of all baseline investigations (echocardiography, MRI and venous blood collection) patients will be randomly assigned to the statin group or to the placebo group. Patients in the statin group will receive 10 mg rosuvastatin per day. The treatment should be continued until the study end (36 months). Follow up investigations will be performed after 12 and 24 months. After 36 months the final investigations will be performed. The MRI measurements will only be repeated at 36 months.

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

Progression of aortic stenosis measured by transthoracic echocardiography.

**Secondary outcome measures**

Progression of aortic dilatation and development of left ventricular hypertrophy measured by MRI and transthoracic echocardiography.

**Overall study start date**

01/11/2005

**Completion date**

01/11/2009

**Eligibility****Key inclusion criteria**

1. Valvular congenital aortic stenosis with a maximum aortic jet velocity  $>2.5$  m/s
2. Age 18-45 years

**Participant type(s)**

Patient

**Age group**

Not Specified

**Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

Both

**Target number of participants**

180

**Key exclusion criteria**

1. Use of statins or other study medication
2. Subvalvular or supra-ventricular aortic stenosis
3. Aortic regurgitation  $>2+$
4. Malignancy within last 2 years
5. Aortic valve replacement in past
6. Rheumatic fever in past
7. Significant concomitant mitral valve disease (MR  $>2+$  or MVA  $<1.5$  cm<sup>2</sup>)
8. History of HMG-CoA reductase inhibitor hypersensitivity
9. Active liver disease

10. Muscular/neuromuscular disease
11. CPK >3 x upper limit of normal (>600 U/l)
12. Renal impairment (creatinine >200 umol/l)
13. Women contemplating pregnancy within next 5 years
14. Pregnant/breast-feeding women
15. Women of childbearing potential not using appropriate contraception
16. Use of cyclosporine

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

01/11/2009

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Erasmus Medical Center

Rotterdam

Netherlands

3000 CA

## Sponsor information

**Organisation**

Erasmus Medical Center, Department of Cardiology (Netherlands)

**Sponsor details**

P.O. Box 2040

Rotterdam

Netherlands

3000 CA

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/018906e22>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Medical Center, Department of Cardiology (Netherlands)

## **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