

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

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/08/2008	Condition category 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

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

Study type(s)

Treatment

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(s)

Progression of aortic stenosis measured by transthoracic echocardiography.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Upper age limit

45 years

Sex

All

Key exclusion criteria

1. Use of statins or other study medication
2. Subvalvular or supra-annular 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 cm²)
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)

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Center, Department of Cardiology (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration