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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	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/08/2008	**Condition category** Circulatory System	[_] Individual participant data [_] 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 supravalvular 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)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
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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