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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24714

Source
Nationaal Trial Register

Brief title
PROCAS

Health condition

Aortic valve stenosis, congenital heart defects

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam, Department of Cardiology

Source(s) of monetary or material Support: Erasmus Medical Center, Rotterdam, Department of Cardiology

Intervention

Outcome measures

Primary outcome

Progression of aortic stenosis measured by transthoracic echocardiography.

Secondary outcome

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

Study description

Background summary

The most common fate of a bicuspid aortic valve is aortic stenosis. Calcification of the aortic valve appears to result from an active disease process reminiscent of atherosclerosis. Retrospective clinical studies have shown that statin therapy is associated with a reduced progression of aortic stenosis. However, in a small prospective study of elderly patients with already calcified valves no effect was found. Statins may be beneficial in patients with aortic stenosis due to their LDL-cholesterol lowering effect, and in addition their anti-inflammatory actions may limit the extent of aortic valve calcification. Our hypothesis is that statin therapy reduce the progression of stenosis in young adult patients with congenital aortic stenosis and may prevent calcification of bicuspid aortic valves.

A double blind, randomized, placebo-controlled multicenter study will be conducted, investigating the effect of rosuvastatin on the progression of aortic stenosis in adult patients (18-45 years) with congenital aortic stenosis. Furthermore, the effect of statins on left ventricular hypertrophy will be studied and factors associated with the rate of progression of congenital aortic stenosis will be determined. Patients will be selected using the CONCOR database, a national registry of adult patients with congenital heart disease. 180 patients will be randomized and receive either 10 mg rosuvastatin or a placebo for a total duration of 3 years. Transthoracic echocardiography and venous blood collection will take place every year. MRI will be performed at baseline and after 3 years. The primary efficacy measure will be the progression rate of the severity of aortic stenosis determined by transthoracic echocardiography. Secondary measures will include the progression of aortic dilatation and development of left ventricular hypertrophy measured by echocardiography and MRI.

Study objective

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

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. Hhistory 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 (creatinin > 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 ciclosporin.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2005
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL397
NTR-old	NTR437
Other	: N/A
ISRCTN	ISRCTN56552248

Study results

Summary results
N/A