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

Gepubliceerd: 28-09-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24714

Bron
Nationaal Trial Register

Verkorte titel
PROCAS

Aandoening

Aortic valve stenosis, congenital heart defects

Ondersteuning

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

Overige ondersteuning: Erasmus Medical Center, Rotterdam, Department of Cardiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression of aortic stenosis measured by transthoracic echocardiography.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2005
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A