High dose statins in post-coarctectomy patients.

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High dose statins will reduce atherosclerosis in post-coarctectomy patients.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22766

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Atherosclerosis in post-coarctectomy patients.

Ondersteuning

Primaire sponsor: ICIN
Overige ondersteuning: ICIN

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

IMT.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Coarctation of the aorta is typically a discrete narrowing of the thoracic aorta just distal to the left subclavian artery. Coarctation of the aorta is a common malformation, accounting for 6 to 8 percent of all congenital heart defects.

The major clinical manifestation in adults with coarctation of the aorta is hypertension in the upper extremities, diminished or delayed femoral pulses, and low or unobtainable arterial blood pressure in the lower extremities. Although the blood pressure typically falls after successful repair, persistent or recurrent hypertension and disproportionate systolic hypertension with exercise are not uncommon.
Normotensive patients, especially those repaired at an older age, often have an exaggerated rise in systolic pressure in response to exercise. The factors responsible for the persistent risk of hypertension after coarctation repair are not well understood.

Studies have shown decreased survival rates in post-coarctectomy patients.

1. The most common cause of this premature death was coronary artery disease, followed by sudden death, heart failure, cerebrovascular accident and ruptured aortic aneurysm.

Intima-media thickness (IMT) is nowadays considered a validated and reproducible endpoint for atherosclerosis.

2. In post-coarctectomy patients carotid IMT is significantly increased.

3. Where femoral IMT is similar, or even decreased, if compared to unaffected controls. Statin treatment might prevent upper arterial tree damage and lead to a reduced number of cardio- and cerebrovascular events regression of existing damage in the main arteries of these patients. In a recent study of by Shukla et al.

4. It was shown that low-dose statins reduced progression of atherosclerosis as observed by carotid intima thickness in patients with known coronary heart disease and normal lipid values independent of lipid lowering. The study favours use of this therapy in patients with normal cholesterol levels. A large intervention trial in post – coarctectomy patients is needed to confirm the benefit of statin treatment on the long term outcome in these patients.

Objective: to reduce progression of atherosclerosis in post-coarctectomy patients.

Study design: multi-centre, prospective, open label blinded endpoints evaluation of patient outcomes. Follow-up three years.

Study population: over 200 post – coarctectomy patients in the Academic Medical Centre in Amsterdam, University Medical Centre in Utrecht and University Hospital St. Radboud Nijmegen, Netherlands.

Intervention: one group daily receives a 80 mg tablet of atorvastatine, the other group will not use any anti-lipaemic medication.
Main study parameter: the main study parameter is change in carotid IMT, determined by ultrasonography.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: all investigations, blood analysis excepted, are non-invasive and free of risk. The burden for the patients mainly consists of the time that is consumed by the investigations, namely: history taking + physical examination (15 min); Quality-of-Life score (15 min); laboratory tests (lipids, glucose, renal function, liver function, CPK); EKG (10 min); Holter-EKG (10min/24h); exercise testing; echocardiogram (30 min); IMT measurement (1/2 hour); MRI (1/2 hour); FMD (1/2 hour).

Possible side effects of Atorvastatin:
Serious side effects in a small number of people:

1. Rhabdomyolysis and myalgia: muscle weakness or pain, sometimes in combination with fever or tiredness. Rhabdomlyolysis may lead to increased CK serum levels and decrease renal function;

2. Decreased liver function.

The most common side effects of Atorvastatin are:

1. headache;

2. constipation;

3. diarrhea;

4. rash.

These side effects often disappear by themselves.

5. The efficacy and safety of atorvastatin 80 mg daily has been shown in several studies.

6. Treatment with atorvastatin resulted in regression of carotid IMT in the ASAP study

We are expecting reduced IMT in the group treated with Atorvastatin over the three year follow-up period, which would be a major benefit for post-coarctectomy patients.

Doel van het onderzoek

High dose statins will reduce atherosclerosis in post-coarctectomy patients.

Onderzoeksproduct en/of interventie

Atorvastatin 80 mg once a day.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Post-coarctectomy patients.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Incapable of giving informed consent;

2. Hypersensitivity to atorvastatin or any of its help substances;

3. Current treatment with anti-lipaemic drugs;

4. Indication for treatment with statins based on the CBO-guideline for cardiovascular risk management;

5. Raised plasma transaminases level > three times limiting value;

6. Raised CPK level > five times limiting value;

7. Myopathia;

8. Pregnant or nursing women (a pregnancy test is offered to every female patient within the fertile age);

9. Desire to have children within the study period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1032
NTR-old	NTR1065
Ander register	: 1980 wordt aangevraagd
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A