

Follow up of IMT in post-coarctectomy patients

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to evaluate progression of IMT in post-coarctectomy patients in 7 years follow up.

| | |
|------------------------------|------------------------------|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Congenital cardiac disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON33815

Source

ToetsingOnline

Brief title

Follow up of IMT in post-coarctectomy patients

Condition

- Congenital cardiac disorders

Synonym

coarctation, congenital narrowed aorta

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ICIN

Intervention

Keyword: atherosclerosis, coarctation, IMT

Outcome measures

Primary outcome

IMT

Secondary outcome

bloodpressure

bloodpressure during exercise

valve dysfunction

left ventricular mass and function

recoarctation

glucose

cholesterol

length

weight

waist line

quality of life

Study description

Background summary

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.

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 patients¹. 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 atherosclerosis². A study in 137 post-coarctectomy patients, median age 29,7 years, performed in the Academical Medical Centre Amsterdam, VU medical centre Amsterdam and University Medical Centre Leiden in 2001-2002, showed an increased IMT in this group of patients³.

In the healthy population, annual progression of IMT is ranging from 0.0085 ± 0.0195 mm⁴, depending on race, gender and arterial wall segment.

Though we know post-coarctectomy patients suffer from accelerated atherosclerosis, little is known about progression of IMT in these patients.

Analysing progression of IMT might give more insight in the pathophysiology of the accelerated atherosclerosis in this group of patients.

Study objective

to evaluate progression of IMT in post-coarctectomy patients in 7 years follow up.

Study design

observational follow up study

Study burden and risks

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); ambulatory blood pressure measurement (10min/24h); exercise testing; echocardiogram (30 min); IMT measurement (1/2 hour); MRI (1/2 hour); Pulse wave analysis (1/2 hour)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

post coarctectomy patients who participated in a previous IMT-study performed in the AMC-, LUMC and VUmc-hospital in 2001-2002

Exclusion criteria

Incapable of giving informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-08-2008
Enrollment: 137
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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 |
|----------|----------------|
| CCMO | NL24186.018.08 |