

IMT measurements during the follow-up of children after Kawasaki disease: the necessity for a control group.

Published: 09-12-2013

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To investigate whether children with a history of Kawasaki disease have an increased IMT and arterial stiffness compared to their healthy siblings.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40375

Source

ToetsingOnline

Brief title

IMT in healthy children and teenagers

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Arterial hardening, Atherosclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Stinafo

Intervention

Keyword: Atherosclerosis, IMT, Kawasaki disease

Outcome measures

Primary outcome

- IMT of the right and left carotid artery (communis, bulb and internal artery).
- Arterial stiffness of the left and right carotid artery.

Secondary outcome

None

Study description

Background summary

Kawasaki disease is a generalised vasculitis of the small and medium arteries. The illness manifests as a febrile illness in young children, mostly under 5 years of age. The most prominent complication is the occurrence of coronary aneurysms. Kawasaki disease is the most common cause of acquired heart disease in children.

Patients with persisting aneurysms have an increased risk for myocardial perfusion disorders, myocardial infarction and acute cardiac death because of progressive stenosis and thrombosis of the aneurysm.

At this moment there is insufficient knowledge about the long term effects of Kawasaki disease, especially for children without coronary aneurysms. Previous histopathological and functional studies (coronary flow reserve, endothelial function, arterial stiffness) show signs of an increased cardiovascular risk pattern, even though these studies are not definite.

The Intima Media Thickness (IMT) is the thickness of the inner two layers (intima-media) of an artery. It can be measured using ultrasound (B-Mode). IMT is a validated method to evaluate the cardiovascular risk. During the same ultrasound the distensibility of the artery is measured; a marker for arterial stiffness.

Since 2002 IMT measurements are done in children visiting the Kawasaki outpatient clinic in the AMC.

With this study we want to compare the IMT of children after Kawasaki disease

with healthy controls to evaluate whether there is a increased IMT and stiffness (and a possible increased cardiovascular risk).

Study objective

To investigate whether children with a history of Kawasaki disease have an increased IMT and arterial stiffness compared to their healthy siblings.

Study design

Prospective, longitudinal.

Study burden and risks

There are no risks involved in the ultrasound examination. This examination is safe, has no radiation, is pain free and does not have side effects.

A disadvantage of the study is a visit to the AMC. The burden of the actual examination includes lying still for about 20 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 7 and 30
- First degree relative with a history of Kawasaki disease

Exclusion criteria

- A history of Kawasaki disease
- A known history of cardiac illness or other (chronic) disease.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2014
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date: 09-12-2013

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 12-06-2014

Application type: Amendment

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	NL46804.018.13