Etiology, course and long-term effects of Kawasaki disease

Published: 08-10-2012
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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON50455

Source
ToetsingOnline

Brief title
Kawasaki disease study

Condition

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

Synonym
Kawasaki disease, mucocutaneous lymph node syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Fond Kind & Handicap (voorheen Stichting Stinafo)

Intervention

Keyword: Etiology, Immunogenetics, Kawasaki disease, Risk factors

Outcome measures

Primary outcome

1. Causative agents: one or more viruses / bacteria involved in triggering

Kawasaki disease

2. Genetics: genetic variations in the human genome is associated with disease

susceptibility, course of the disease (coronary artery aneurysms), and the

clinical reaction to standard treatment with IVIG

3. Biomarkers: generate novel diagnostic tests

4. Long-term effects: assessment of a cardiovascular risk profile

Secondary outcome

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Study description

Background summary

Kawasaki disease is an acute systemic vasculitis in childhood, in which coronary artery aneurysms can develop as a complication. Kawasaki disease is the leading cause of acquired heart disease in childhood.

Standard treatment consists of a single infusion of high dose intravenous immunoglobulin (IVIG) and acetylsalicylic acid (aspirin). Coronary artery aneurysms develop in more than 25% of untreated children. Studies have shown that treatment with IVIG has reduced this risk to less than 10%. The majority of patients recover quickly after the start of the IVIG treatment, but approximately 15-20% of children do not respond to this standard treatment. Children who are unresponsive to IVIG have an increased risk of developing aneurysms.

Although Kawasaki disease was first described in 1967, the cause of the disease

is still unknown. Since no causative pathogen(s) have been found, it is not clear which children are susceptible to Kawasaki disease. There is no test to diagnose Kawasaki disease. Difference in incidences observed between different ethnic populations and the results of twin studies, make it likely that the genetic predisposition of the child also plays a role. The SARS-CoV2 pandemic has proven that a prior infection can trigger Kawasaki disease, and can present in some children with symptoms of shock, previously diagnosed as the so-called Kawasaki disease shock syndrome.

Questions about the future of these patients are also important. Are only children with coronary aneurysms at increased risk of cardiovascular diseases in later life, or are unaffected children also at risk due to the prior vasculitis? Previous studies are limited and often inconclusive.

Study objective

The objective is to gain more insight in:
1. Possible causative agents of Kawasaki disease. At the moment no single causative agent has been identified despite the strong suspicion of an infectious etiology of the disease.
2. Genetic factors related to susceptibility and disease course of Kawasaki disease.
3. Biomarkers to help diagnose Kawasaki disesae with increased certainty.
4. Influence of this pediatric vasculitis on long term cardiovascular outcome measures.

Study design

Prospective, cross-sectional and (partly) longitudinal study

Study burden and risks

Additional blood and body fluids for microbial tests (microbiome analysis; DNA analysis).

Another disadvantage of study participation is the traveling time for the families to visit our multidisciplinary outpatient care unit at the AMC (instead of the nearby hospital of admission) after the acute onset of disease. During this standard visit the extra blood withdrawal for our study will be combined with the standard blood tests.

Contacts

Public

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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

- Diagnosis of Kawasaki disease according to a standard set of clinical criteria
- Kawasaki disease between the age of 0-18 years
- Inclusion of 300 new cases per 5 years (there are about 100 cases per year in The Netherlands), which would be 600 cases over the next 10 years.

Exclusion criteria

None.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2013
Enrollment:	850
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-10-2020
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

ID: 21895
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41023.018.12
OMON	NL-OMON21895