Kawasaki Studie

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The objective of to gain more insight in: - Possible causative agents of Kawasaki disease. At teh moment no single causative agent has been identified despite the strong suspicion of an infectious etiology of the disease. - Genetic factors...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21895

Bron
Nationaal Trial Register

Aandoening

Kawasaki disease

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: Stinafo

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Causative agents: one or more viruses/bacteria involved in triggering Kawasaki disease
- Genetics: genetic variation in the human genome (.g. single nucleotide polymorphisms (SNP's) in the IgG receptor and the clinical reaction to standard treatment with IVIG).
- Long-term effects: assessment of a cardiovascular risk profile.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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 15-25% of untreated children. 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. 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.

Objective of the study:

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. Influence of this pediatric vasculitis on long term cardiovascular outcome measures.

Study design:

Prospective, cross-sectional and (partly) longitudinal study

Study population:

All patients diagnosed with "Kawasaki disease" (according to the diagnostic criteria) in the participating centers will be asked to participate in the study.

Primary study parameters/outcome of the study:

1. Causative agents: one or more viruses / bacteria involved in triggering Kawasaki disease
2. Genetics: genetic variation in the human genome (e.g. single nucleotide polymorphisms [SNPs] in the IgG receptors (i.e. Fc-gamma receptors) is associated with disease susceptibility, course of the disease (coronary artery aneurysms), and the clinical reaction to standard treatment with IVIG
3. Long-term effects: assessment of a cardiovascular risk profile

Secundary study parameters/outcome of the study (if applicable):

-
Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
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) at 6-12 months 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. During the ultrasound examination of the neck vessels, the patient must lie as still as possible, which can be difficult for a young child. The ultrasound examination will not exceed 20 minutes, is painless and has no known side- or after-effects.

Doel van het onderzoek

The objective of to gain more insight in:

- Possible causative agents of Kawasaki disease. At teh moment no single causative agent has been identified despite the strong suspicion of an infectious etiology of the disease.

- Genetic factors related to susceptibility and disease course of Kawasaki disease.

- Influence of this peadiatric vasculitis on long term cardiovascular ourcome measures.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

S.M. Dietz
[default]
The Netherlands

Wetenschappelijk

S.M. Dietz
[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of Kawasaki disease according to a standard set of clinical criteria

- Kawasaki disease between teh afe of 0-18 years

- Inclusion of 250 new cases over de next 5 uears (there are about 100 cases per year in the Netherlands).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50455
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3892
NTR-old	NTR4054
CCMO	NL41023.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON50455

Resultaten

Samenvatting resultaten
N/A