Wheezing Illnesses Study Leidsche Rijn/ Adolescents

Published: 19-12-2018
Last updated: 12-10-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON54512

Source
ToetsingOnline

Brief title
WHISTLER Adolescents

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)
- Vascular disorders NEC

Synonym
asthma and well-being of children in puberty

Health condition

mentaal welzijn en veerkracht

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Stichting Tetri

Intervention

Keyword: Adolescence, Cardiovascular diseases, Chronic lung diseases, Quality of life

Outcome measures

Primary outcome

Part 1: cIMT and PWV as cardiovascular outcomes.

Part 2: lung function measurements (spirometry).

Part 3: QoL, happiness, well-being and resilience will be measured using

validated questionnaires.

Part 4: different markers of disease activity defined through questionnaires,

physical examination and markers in the blood,

depending on the chronic disorder, will be examined in the WHISTLER population.

Secondary outcome

Part 1: Carotid artery distension using ultrasound. Endothelial functioning

using flow mediated dilation. Dyslipidemia using a lipid panel including total

cholesterol, total triglycerides, apolipoprotein B (ApoB), lipoprotein a

(Lp(a)), HDL- and LDL-cholesterol and HbA1c. Inflammation

using CRP levels. Intra-abdominal and subcutaneous fat measured by ultrasound.

Part 2: Allergic sensitization patterns and specific IgE-profiling in the blood

next to reported allergies by a questionnaire.

Part 3: Biological stress marker hair cortisol.

Study description

Background summary

The present protocol contains four separate parts with different backgrounds that together form the Wheezing Illnesses, Study Leidsche Rijn (WHISTLER). Two of these parts will be a follow-up on the earlier phases of the WHISTLER cohort; the third part will extend its focus to the impact of chronic conditions on resilience and happiness of affected children, and the fourth part will enhance the scope of the WHISTLER population as a healthy reference group to children with a chronic disorder.

Part 1: The relation between early childhood risk factors and later cardiovascular health.
Since the process of atherosclerosis is known to begin in early childhood, cardiovascular diseases become a major threat for children*s health. The best way to assess cardiovascular health in the pediatric population is relatively unchartered territory.
Atherogenesis initiates in the iliac arteries and abdominal aorta, and subsequently develops in higher regions of the arterial tree.
Modifiable risk factors such as obesity, hypertension, hyperlipidemia, and hyperglycemia accelerate atherogenesis in the young.
Multisite and multimodal assessment of early atherosclerosis is encouraged to capture the complexity of atherosclerosis as a systemic disease. Next to conventional carotid intima-media thickness measurements, implementation of aortic pulse wave velocity measurements and flow mediated dilation can advance the assessment of early atherosclerosis in pediatrics.

Part 2: The impact of diminished early life lung function on the development of asthma.
Wheezing respiratory illnesses represent the most common cause of morbidity and mortality in infancy and childhood. From the age of about 4 years 10 - 15% of children present with wheezing due to atopic asthma. It has been suggested that abnormal early life lung function is associated with wheezing during later life. However, data are scarce and results conflicting. The WHISTLER study measured neonatal lung function of almost 2500 babies at young age and in a subset of these children (N=1000) lung function measurements are repeated at age 5 and 8 years. Within this follow-up part we can further study the association between abnormal early life lung function and the development of wheezing and asthma during adolescence. Since atopic individuals are often sensitive to multiple allergens (e.g. food or inhalant allergens) it would be

interesting to identify the allergic sensitization patterns in atopic individuals and the possible differences with non-atopic individuals in childhood and adolescence and evaluate these sensitization patterns over time.

Part 3: The impact of chronic conditions on resilience and happiness of affected children in adolescence age.
Over years healthcare has improved significantly with the result that earlier defined life-threatening diseases are more often controlled or stabilized. Consequently, the prevalence of chronic diseases, such as asthma increased. It is known that one out of four children grows up with a chronic disease. Having a chronic disease during childhood influences daily and future life. Evaluating resilience in affected children, which is defined as maintaining or regaining mental health after exposure to severe psychological or physical stress, would therefore be of great value.

Part 4: The WHISTLER population as a reference group for children with a chronic disorder.
A unique added value of WHISTLER is the possibility to compare outcomes of children with various chronic conditions (e.g., metabolic, endocrine disorders) followed up in the Wilhelmina Children*s Hospital (WKZ) with healthy peers from the general population. These collaborations make it possible to distinguish disease-related symptoms from healthy phenomena, which could have important implications for the child, parents and treating physician.

Study objective

Primary objectives are displayed here.
Part 1: Establish the effect of early life cardiovascular risk factors on pre-clinical atherosclerosis in adolescents.
Part 2: Identify the impact of diminished early life lung function on lung function during adolescence and investigate the development of asthma.
Part 3: Determine the impact of various determinants of health (e.g. chronic diseases, socio-economic status, sleep,) on QoL, happiness, and resilience in adolescents.
Part 4: Distinguish disease-related symptoms from healthy phenomena in children with various chronic conditions using the WHISTLER population as a healthy reference group.

Study design

The WHISTLER study is a birth cohort study. The present study contains a follow up measurement of the WHISTLER study at the age of approximately 12-18 years.

Study burden and risks

Nature and extent of the burden and risks associated with participation:
The burden and associated risks with participation are low. Of all measurements performed in this study, only the venipuncture is an invasive procedure with low associated risks. This follow-up will consist of one visit to the WKZ (1,5 to 2 h) and a questionnaire filled in at home (1 h).

Benefit associated with participation:
There is no individual benefit for the children and adolescents participating in this study. Participation will be completely voluntary.
They will receive a ¤20,00 VVV gift voucher as a thank you for participating, after completing the online questionnaire. Furthermore, parking costs will be reimbursed.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Children who reached the age of 12-18 years and who already participated in the WHISTLER-0 and/or WHISTLER/Cardio and/or WHISTLER/Cardio2 study, and who's parents and child are willing to give informed consent to participate in this study. From age 16, informed consent will be obtained from the adolescent only. Children and adolescents aged 12-18 years who already participated in the WHISTLER round aged 12-16 years consisting of only online questionnaires, because of the corona epidemic, will be included. This group, which consists of around 300 children, will be approached for this new WHISTLER/ Adolescent round since it consists of new physical measurements and an amended online questionnaire.

Exclusion criteria

There are no exclusion criteria.

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):	12-03-2019
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-07-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-08-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-11-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-03-2023

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-10-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL66918.041.18