

The variability of urinary albumin excretion and prevalence of microalbuminuria in young children

Published: 25-03-2015

Last updated: 21-04-2024

Phase 1:- The main objective of this phase of the study is to determine the variation of UAC over 8 weeks time in toddlers. - The secondary objective of this phase is to determine the variation of UAC over 3 days time. Phase 2:- The main objective of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON41927

Source

ToetsingOnline

Brief title

Albumiuria in young children

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym

microalbuminuria, proteins in the urine

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiovascular risk, children, microalbuminuria, variability

Outcome measures

Primary outcome

Phase 1: The coefficient of variation (CV) of UAC calculated over 8 weeks time.

Phase 2: The percentage babies and toddlers with a geometric mean of UAC > 20mg/L.

Secondary outcome

Phase 1: The CV of UAC calculated over 3 days

Phase 2: The correlation of log transformed UAC with several parameters obtained from a questionnaire.

Study description

Background summary

Increased urinary albumin excretion (UAC) has been established as an important determinant of renal and cardiovascular risk. A possible hypothesis is that an increased albuminuria entails an increased cardiovascular risk is caused by a congenital variation and quality of the peripheral vasculature.

In recent studies, prevalence of increased albuminuria in the general population of approximately 5 * 8% is found. A prevalence of approximately 7% has been found in children of 20-40 months old. These data could support the hypothesis.

However, these data are based on one single measurement. Little is known about the day to day variation and the variation throughout the day of albuminuria in children; is it a continuous value, or is an increased value an intercurrent event?

Study objective

Phase 1:

- The main objective of this phase of the study is to determine the variation of UAC over 8 weeks time in toddlers.

- The secondary objective of this phase is to determine the variation of UAC over 3 days time.

Phase 2:

- The main objective of this phase is to determine the prevalence of microalbuminuria in this study population.
- The secondary objective of this phase is to investigate the correlation of several parameters of child and parents obtained from a questionnaire.

Study design

This is a prospective cohort study

Study burden and risks

No risk is associated with participation in this study. Only an amount of urine samples will be collected. This is no burden for the children, but somehow for the parents because they have to perform extra actions when changing the diaper. When an abnormal high UAC (>200 mg/L) is found, parents will be informed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- age 12-48 months

The inclusion of participants will be divided in two phases. In the first phase, 110 participants will be included, in which the variability of albuminuria will be studied. In the second phase an additional number of toddlers in the same age range will be included to determine the prevalence of microalbuminuria over the total study population. Once we know the day-to-day variability in albuminuria in this population we will be able to perform a power calculation to determine the sample size for phase 2 of the study.

Exclusion criteria

- Known renal disease of the child
- Current infection of the urinary tract

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-05-2015

Enrollment: 110

Type: Actual

Ethics review

Approved WMO

Date: 25-03-2015

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 25-11-2015

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 21-01-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50374.042.14