THE KIMONO-study - on the development of renal injury in children with a solitary functioning kidney.

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THE KIMONO-STUDY is designed to study the consequences of having an SFK from childhood. Furthermore, a tailor made risk profil will be designed for children with an SFK, based on individual risk factor (for example co-morbidity, genetic aberrations...

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

Summary

ID

NL-OMON37570

Source
ToetsingOnline

Brief title
THE KIMONO-STUDY

Condition

- Other condition
- Renal and urinary tract disorders congenital
- Genitourinary tract disorders NEC

Synonym
single kidney, Solitary functioning kidney

Health condition

Genetica

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Fonds NutsOhra Zorgsubsidies te Amsterdam.

Intervention

Keyword: Genetics, Hyperfiltration hypothesis, Renal injury, Solitary functioning kidney

Outcome measures

Primary outcome

KIMONO PRO: Prevalence of renal injury (defined as hypertension, proteinuria

and/or a decrease in glomerular filtration rate) in children with an SFK.

KIMONO GENE: Identification of new genetic mutations prevalent in children with

an SFK.

KIMONO BEGIN: National incidence of SFK.

Secondary outcome

KIMONO PRO: Devolpment of *early* markers for renal injury.

KIMONO GENE: Prevalence of genetic mutations.

KIMONO BEGIN: Follow-up of a cohort of children with an (antenatally diagnosed)

SFK.

Study description

Background summary

Children with a solitary functioning kidney (SFK) are at increased risk to develop renal injury from childhood onwards. However, specific risk factors are unknown and consensus about clinical follow-up is absent.
An SFK can be of congenital origin (caused bij unilateral renal agenesis or

multicystic dysplastic kidney disease), but can also be acquired due to unilateral nephrectomy in childhood caused by underlying disease.
We hypothesize that children with both types of SFK will have an increased risk for renal injury. This is most likely caused by renal mass reduction, which sets a vicious cycle of hyperfiltration leading to glomerulosclerosis and an ongoing loss of nephrons. In the long run, renal injury comes to clinical expression as hypertension, proteinuria and a decrease in glomerular filtration rate. This 'hyperfiltration hypothesis', designed by Brenner and co-workers, however is only confirmed in human studies.
THE KIMONO STUDY will test the hyperfiltration hypothesis in children with an SFK.

Study objective

THE KIMONO-STUDY is designed to study the consequences of having an SFK from childhood. Furthermore, a tailor made risk profil will be designed for children with an SFK, based on individual risk factor (for example co-morbidity, genetic aberrations etc.).

Study design

THE KIMONO-STUDY consists of 3 separate studies:
* KIMONO PRO has a cross-sectional study design on parameters for renal injury in children with an SFK
* KIMONO GENE performs genetic analysis in children with an SFK
* KIMONO BEGIN is an epidemiological study and determines the national incidence number of children with an SFK. Also a prenatally diagnosed cohort will be designed.

Study burden and risks

THE KIMONO-STUDY is specifically designed to be performed in children. The nature and extent of the burden and risks associated with participation to this study are limited, or even absent. An extra blood sample will be drawn together with a subsequent urine sample which is partly used for proteomics. Furthermore, a 24h ambulatory blood pressure measurement will be perfomed and children and their parents will be asked to fill in a non-invasive questionaire.

The study parameters of THE KIMONO-STUDY could be of importance in the prevention of the development of diseae as well as to hamper unnecessary 'hospitalization' of these children. In the long run, we therefore hold the opinion that participation to this study is beneficial for children with an SFK.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age <18 yrs
Solitary functioning kidney (from congenital or acquired origin, defined as <10% activity on DMSA-scan)

Exclusion criteria

- treatment for malignant disease during study protocol
- absent informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	04-04-2012
Application type:	First submission
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	NL39074.029.12