

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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: Development 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 by 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 performed and children and their parents will be asked to fill in a non-invasive questionnaire.

The study parameters of THE KIMONO-STUDY could be of importance in the prevention of the development of disease 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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### Scientific

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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