THE KIMONO-STUDY.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23298

Source
Nationaal Trial Register

Brief title
KIMONO (KIdney of MONofunctional Origin)

Health condition

- Glomerular hyperfiltration
- Solitary functioning kidney
- Congenital Anomalies of the Kidney and Urinary Tract
- Children
- Chronic Kidney Disease
- Hypertension
- Proteinuria
- Genetics

Sponsors and support

Primary sponsor: VU University Medical Center. Amsterdam, The Netherlands.
Source(s) of monetary or material Support: THE KIMONO-STUDY is funded by a grant from Fonds NutsOhra Zorgsubsidies, Amsterdam (project-number 1101-058) and Pfizer BV., Capelle a/d IJssel (study-number WS291861), The Netherlands.

Intervention

Outcome measures

Primary outcome

1. Proportion of children with signs of renal injury (hypertension, proteinuria, chronic kidney disease);

2. Genetic malformations (CNV, SNPs).

Secondary outcome

1. GFR;

2. Blood pressure;

3. Developmental age of renal injury;

4. General incidence;

5. Meta-analysis data.

Study description

Background summary

Congenital anomalies of the kidney and urinary tract (CAKUT) are the major cause of end-stage renal disease in childhood. One important subgroup of CAKUT-patients consists of children with solitary functioning kidneys. A solitary functioning kidney from childhood can be of congenital origin or can also be acquired after unilateral nephrectomy. Both types of solitary functioning kidney have been associated with an increased risk to develop chronic kidney disease in later life. This risk may be caused due to glomerular hyperfiltration in the reduced number of nephrons following renal mass reduction, as described by Brenner. No new nephrons can be formed after the 34-36th week of gestation, which implies that glomerular hyperfiltration is present in a solitary functioning kidney. Another significant risk factor in the development of chronic kidney disease is the high prevalence of associated CAKUT found in patients with a solitary functioning kidney. Finally, genetic factors that play a role in renal development have incrementally been identified to underlie the solitary functioning kidney.
THE KIMONO-STUDY aims to develop an individualized risk profile for children with a solitary functioning kidney by performing studies on the development of renal injury, genetics and epidemiologyl.

Study objective

The hyperfiltration hypothesis implies that children with a solitary functioning kidney are at risk to develop hypertension, (micro)albuminuria and chronic kidney disease. We aim to develop an individualized risk profile for children with a solitary functioning kidney based on renal parameters, genetics and epidemiological studies.

Study design

Cross-sectional studies.

Intervention

1. Gold standard GFR measurement;

2. 24h blood pressure monitoring;

3. Genetical studies (eg NextGen Exome sequencing, Copy Number Variation analysis);

4. Questionaires.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with an congenital or acquired solitary functioning kidney;

2. Age 0 - 21 years.

Exclusion criteria

1. Renal function on DMSA > 10%;

2. A solitary functioning kidney after renal transplant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-12-2012
Application type:	First submission

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
NTR-new	NL3597
NTR-old	NTR3748
Other	VUmc : 1101-058
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Westland R, Kurvers RAJ, Wijk JAE van, Schreuder MF. Risk factors for renal injury in children with a solitary functioning kidney. Pediatrics ePub Feb 2013
2. Westland R, Schreuder MF, Bökenkamp A, Spreeuwenburg MD, Wijk JAE van. Nierschade bij kinderen met een mononier – DE KIMONO-STUDIE. Tijdschrift voor Kindergeneeskunde (6 december 2012).
3. Westland R, Wijk JAE van, Schreuder MF. The reason why mother nature provided us with two kidneys: the risks of a congenital solitary functioning kidney. Nephrol Dial Transplant. 2012 Jun;27(6):2603-4. Epub 2011 Nov 5.
4. Westland R, Schreuder MF, Bökenkamp A, Spreeuwenburg MD, Wijk JAE van. Renal injury in children with a solitary functioning kidney - THE KIMONO STUDY. Nephrol Dial Transplant 2011; 26: 1533-1541.
5. Schreuder MF, Westland R, Wijk JAE van. Unilateral multicystic dysplastic kidney: a meta-analysis of observational studies on the incidence associated urinary tract malformations and the contralateral kidney. Nephrol Dial Transplant 2009; 24: 1810-1818.