Hyperfiltration hypothesis in children with a solitary functioning kidney: an assessment of glomerular function by single shot inulin clearance - THE KIMONO-STUDY

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

Summary

ID

NL-OMON31785

Source
ToetsingOnline

Brief title
KIMONO - kidney of monofunctional origin

Condition

- Renal disorders (excl nephropathies)

Synonym
single kindey, solitary functioning kidney

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Farmaceutische industrie,Pfizer

Intervention

Keyword: children, glomerular function, glomerular hyperfiltration, solitary functioning kidney

Outcome measures

Primary outcome

Based on "Study design":

Ad 1. Glomerular filtration rate (in ml.min/1.73m²), assessed by single shot

inuline clearance

Ad 2. Anthropometric data: waist-hip ration, subscapular skinfold thickness.

Ad 3. Blood- and urine evaluation on concentrations of the following markers:

plasma-renin activitiym ACE-polymorphisms, aldosterone, cystatin C, HbA1C, Von

Willebrand-factor, cholesterol and homocystein.

Secondary outcome

See primary study parameters/outcome of the study

Study description

Background summary

The hyperfiltration hypothesis is designed by Brenner and co-workers around 1980 and states that a reduction in renal mass and therefore a lower number of nephrons triggers a pathological vicious cycle. In the long run, this cycle may result in hyperfiltration injury clinically coming to expression as hypertension, proteinuria and chronic kidney disease. However due to

methodological limitations a different approach is required to study the phenomenom of hyperfiltration in humans.
One such an approach is to study children with a solitary functioning kidney. Not only these children have a reduction in renal mass, but also this condition is present from childhood onwards. This implies a long time exposure to the vicious cycle of hyperfiltration in these children. Several studies report about hyperfiltration in man with a solitary kidney from childhood onwards, with inconclusive results. However, only two studies are known that used an inuline clearance to evaluate glomerular filtration rate.
Two reports with a retrospective design from our research group have shown that more than half of all children with a solitary functioning kidney have hypertension, (micro)albuminuria or chronic kidney disease. Furthermore a developed prediction model showed that glomerular filtration begins to decline progressively in these children from 10 yrs of age onwards. These results can be interpreted as possible hyperfiltration injury, implying that these children are at risk for chronic renal disease in later life. However our retrospective studies, as many other reports, used the Schwartz-formula to estimate glomerular function in these children. The KIMONO-STUDY is designed to assess exact glomerular function by inulin clearance, which is known as the gold standard technique for glomerular filtration rate.

Study objective

This study evaluates glomerular function in children with a solitary functioning kidney. Furthermore anthropometric data is gathered about waist-hip ratio and subscapular skinfold thickness. Anthropometric characteristics can be both a cause as an effect of impaired glomerular function in hyperfiltration hypothesis. To evaluate early renal dysfunction, recently discovered markers are assessed in blood and urine.
The KIMONO-STUDY serves the purpose to study the hyperfiltration hypothesis in humans and evaluates the results from our earlier retrospective studies. The main aim of this study is to answer the question whether or not children with a solitary kidney are truly at risk for developing chronic renal disease in later life.

Study design

The KIMONO-STUDY contains the following tests:

1. Inulin clearance by single shot injection method
2. Anthropometric data about waist-hip ratio and subscapular skinfold thickness.
3. Extended blood- and urine evaluation on parameters for renal dysfunction: plasma-renin activity, ACE-polymorphisms, aldosterone, cystatin C, HbA1C, Von Willebrand-factor, cholesterol and homocystein.

The inulin clearance requires an intravenous line. To reduce the burden of

multiple injections to a minimum, all other actions will be done from this intravenous line. A bolus of inulin is given at the start of the test and blood is drawn from the intravenous line at five marked times.

Study burden and risks

Patients will get an intravenous line. Inulin will be given by single shot method to prevent the child from multiple injections to draw blood. Inulin is an inert sugarpolymer, which can cause only slight hypersensitivity reactions; there are very little other complications. Hypersensitivity is prevented by admission of a antihistaminic agent (clemastine) before the start of the test. At the Pediatric Renal Center the single shot inulin clearance is performed routinely by trained nurses for clinical purposes, who have experience with children in a medical setting. The subscapular skinfold thickness is measured by the scientifically known method.

The KIMONO-STUDY is especially designed to reduce the burden and risks for the participating children to a minimum. In respect to the standard hospital appointment, the study requires an extension at the following points:

• The children have to to stay all morning.

• Blood is drawn from an intravenous line (from which inulin will be adminstrated) in stead of the standard intravenous punction. One more tube of blood will be drawn.

• The inulin clearance requires an intravenous line

• Waist-hip ratio and scapular skinfold thickness will be measured.

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

- solitary functioning kidney
- the child must be over 8 years of age
- informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed

Start date (anticipated):	01-02-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	31-12-2008
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	NL17785.029.08