Consequences of a congenital monokidney in patients with MCKD

Published: 05-01-2010
Last updated: 04-05-2024

Primary Objective: Mapping the consequences of a congenital monokidney on kidney function for children with MCKD.Secondary Objective(s): - Giving recommendations about follow-up for children treated with nephrectomy for MCKD.- Defining better blood...

Ethical review	Not approved
Status	Will not start
Health condition type	Renal and urinary tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON33413

Source
ToetsingOnline

Brief title
ConscmkMCKD

Condition

- Renal and urinary tract disorders congenital
- Renal disorders (excl nephropathies)

Synonym
MCKD; Multicystic kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Nierstichting nederland;mogelijk farmaceutische bedrijven voor specifieke bepalingen.

Intervention

Keyword: hypertension, MCKD, Solitary kidney

Outcome measures

Primary outcome

Previous medical history: parity of mother at birth, gestational age at birth, birth weight, birth length, singleton / multiple pregnancy, urinal and faecal continence, infection of urinary tract, obstipation

Family history: diabetes (type), cardiovascular disease, hypertension, kidney disease / renal anomalies

History: medication, smoking, alcoholintake

Physical examination: height, weight, BMI, waist circumference (waist/hip ratio), blood pressure (measured three times in seating position with a Dinamap oscillometer)

Secondary outcome

Kidney ultrasound: kidneysize (compared to normal deviation), thickness of parenchyma, transverse dimension and if possible kidney length.

Blood sampling: Cystatin-C, NGAL (neutrophil gelatinase-associated lipocalin), creatinine, uric acid, urea, HbA1C, glucose, Calcium and Phosphate

Urinary sampling: TGF-beta1, sediment, screening, albumin/creatinine ratio and protein.

Study description

Background summary

According to the hyperfiltration hypothesis, a low number of nefrons in any human subject will lead to hyperfiltration in the remaining nefrons and this may be associated with systemic hypertension, proteinuria and glomerulosclerosis. Children with a MCKD are born with an enlarged congenital monokidney just as children with unilateral renal agenesis..Unknown is whether these children have a monokidney with normal number of nefrons (hypertrophy) or a monokidney with a higher number of nefrons (hyperplasia) The patients according to the hyperfiltration hypothesis are at risk to develop hypertension, protienuria and glomerulosclerosis.
In 2008 the group of Schreuder1 concluded that there is microalbuminuria and/or hypertension present in 50% of patients with congenital solitary kidneys. According to them this warrants a systematic follow-up of blood pressure, proteinuria and renal function in all patients with congenital monokidneys especially in patients with a low birth weight.
In 2005 Valentini et. al.2 have done a case report about a 10-year old female patient in whom a high index of suspicion of renovascular hypertension existed. Initially she was thought to have unilateral renal agenesis, because only a solitary kidney could be visualizes on both ultrasound and renal scintygraphy. But on MRI investigation she was found also to have an atrophic kidney. A nephrectomy was performed which resulted in complete resolution of her hypertension. It was hypothesised that this remnant kidney could potentially be producing renin and could be responsible for her hypertension.
Schreuder used patients for his study with renal agenesis. The potential confounder as described above was not taken into account. In our patient group this potential confounder is eliminated because all dysplastic remnants have been removed. A systematic review of H. Narchi3 witch included 29 studies with a total of 1115 children concludes there is a mean probability of a child with unilateral MCKD that is managed conservatively of developing hypertension of 5.4 per 1000. Their study could not make firm recommendations on the frequency and duration of blood pressure measurement for these children.
There is sparse information involving the follow-up of children with MCKD. Especially not when they are treated with a nephrectomy. Our population is the largest known population of MCKD patients treated with a nephrectomy. It will ad vital information for future generations of MCKD patients.Is regular follow-up needed in patients with a congenital monokidney? Is the hypertension found in children managed conservatively due to the potential confounder? Does hypertension, proteinuria and glomerulosclerosis occur in our group?

Study objective

Primary Objective: Mapping the consequences of a congenital monokidney on kidney function for children with MCKD.
Secondary Objective(s):
- Giving recommendations about follow-up for children treated with nephrectomy for MCKD.
- Defining better blood test for quantification of kidney function.
- Defining better urine test for quantification of kidney function.

- Quantification of the kidney overgrowth associated with nephrectomy for children with MCKD.

Study design

Follow-up study.
Patients are asked to come for control to the Wilhelmina Children*s hospital. Before the control they are asked to fill in a questionnaire and to participate in the study. The setting will be the Wilhelmina Children*s hospital. The extra time investment for the patient is estimated at 30 min. The duration of the total study is estimated at 6 months.

Study burden and risks

The extra burden for the patients is minimal. The burden is an out patient clinic control with physical examination, ultrasound of the kidney, blood and urine sample. The benefit of the study for the patient is that its renal function will be better monitored. The study is also group related, because recent recommendations suggest a 2-yearly check-up. This to *catch* potential renal failure in an early stage. If the minor participants do not participate, the group will be too small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

MCKD; Nephrectomy;

Exclusion criteria

Heminephrectomy
Conservatively managed
Congenital abnormality contralateral kidney

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	122
Type:	Anticipated

Ethics review

Not approved

Date:	05-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL28729.041.09