

# Nephro-Urological evaluation of a National Prenatal Ultrasound Screening Program of the Fetus

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Objective of this study is the development of a national "best practice guideline on pre and postnatal follow up for prenatally detected abnormalities of the kidney and/or urinary tract". Furthermore, the guideline will be evaluated and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Renal disorders (excl nephropathies)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32317

### Source

ToetsingOnline

### Brief title

PUNC-R Prenatal Urology and Nephrology Children Registration

### Condition

- Renal disorders (excl nephropathies)

### Synonym

Hydronephrosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** ZonMw subsidieaanvraag is ingediend, Nierstichting Nederland

## Intervention

**Keyword:** Cost reduction, Guideline evaluation and validation, Hydronephrosis, Prenatal ultrasound screening

## Outcome measures

### Primary outcome

the health of the child one year after birth

### Secondary outcome

AP diameter of the renal pelvis

Renal length

Unilateral/ bilateral abnormality of the kidney

Grade of hydronephrosis

## Study description

### Background summary

Abnormalities of the kidneys and the lower urinary tract is the most frequent detected abnormality at prenatal ultrasound screening. Of these abnormalities Hydronephrosis is the most frequent finding. The relevance of the prenatally detected hydronephrosis for the postnatal outcome of the child in the Netherlands is not clear.

### Study objective

Objective of this study is the development of a national "best practice guideline on pre and postnatal follow up for prenatally detected abnormalities of the kidney and/or urinary tract". Furthermore, the guideline will be evaluated and validated.

### Study design

Development, implementation, evaluation and validation of a national "best practice guideline on pre and postnatal follow up for prenatally detected abnormalities of the kidney and/or urinary tract".

For this study 1000 pregnant woman of a child with abnormality of the kidney or

lower urinary tract, detected at 20 weeks of pregnancy with ultrasound will be included. Furthermore, 500 pregnant woman of a child in which no abnormality are found at 20 weeks pregnancy with ultrasound are included. Medical data are collected from 20 weeks pregnancy up to one year after birth. Analysis of the data will provide information which children are and which children are not at risk.

### **Study burden and risks**

none

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Children (2-11 years)

## Inclusion criteria

AP diameter of the pyelum in transversaal angle > 5 mm in the unborn child at 20 weeks of pregnancy

## Exclusion criteria

children with syndromale abnormality

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	500
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL20795.091.07