

# The role of urethral obstruction in boys with lower urinary tract symptoms or urinary tract infection.

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To study the outcome in boys with a history of UTI or with persistent incontinence who underwent cystoscopy and endoscopic treatment in case of obstruction, compared to boys who did not have cystoscopy.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Urethral disorders (excl calculi)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON36209

### Source

ToetsingOnline

### Brief title

I-V-O 2

### Condition

- Urethral disorders (excl calculi)

### Synonym

narrowing of the urethra, urethral obstruction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** obstruction, urethra, urinary incontinence, urinary tract infection

## Outcome measures

### Primary outcome

Micturition frequency, voided volume, LUTS, incontinence episodes, episodes of UTI.

### Secondary outcome

Obstipation, additional treatments: training, medication, surgery.

## Study description

### Background summary

Infravesical obstruction in boys may be the cause of urinary tract infection (UTI), lower urinary tract symptoms (LUTS) or incontinence. It is unsure whether cystoscopy with concomitant treatment of obstruction, should be part of the diagnostic protocol in boys after a first UTI within the first year of life (group 1) or in case of persisting urinary incontinence (UI) in boys (group 2).

### Study objective

To study the outcome in boys with a history of UTI or with persistent incontinence who underwent cystoscopy and endoscopic treatment in case of obstruction, compared to boys who did not have cystoscopy.

### Study design

This is an observational cohort study

### Study burden and risks

Two questionnaires and a micturition diary (24 hours).

## Contacts

### Public

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Heidelberglaan 100

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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

Group 1:

- Male sex
- Proven UTI (urinary tract infection)
- Age <12 months of age at time of UTI
- Presenting with UTI between January 2004 and December 2007 in the Wilhelmina Children's Hospital Utrecht OR presenting with UTI between 2002 and 2005 in the Emma Children's Hospital Amsterdam
- Willing and able to participate in the study
- Signed informed consent;

Group 2:

- Male sex
- age < 18 years

- UI despite 1 year of conservative treatment
- Cystoscopy in the Wilhelmina Children's Hospital Utrecht between January 2007 and December 2009 AND suspicion of infravesical obstruction OR tertiary referral for incontinence to the Erasmus Medical Center Rotterdam between 2006 and 2009
- Willing and able to participate in the study
- Signed informed consent

## Exclusion criteria

Neurogenic bladder disorder or suspicion of neurogenic bladder disorder  
 (Suspicion of) UPJ-stenosis  
 Previous cystoscopy  
 Cystoscopy in combination with other treatment of the upper urinary tract (e.g. deflux injections, pyeloplasty, ureteral reimplantation)  
 Mental retardation  
 Syndromal disorder  
 Hypospadias

## 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:	Treatment

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	565
Type:	Anticipated

## Ethics review

Not approved

Date: 13-10-2011

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	NL36457.041.11