

# Long term follow up after transurethral treatment of infravesical obstruction in boys

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The goal of this study is to investigate the long term results after transurethral treatment of infravesical obstruction in boys with respect to LUTS, incontinence, urinary tract infections, coping style and quality of life, and possible...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Urethral disorders (excl calculi)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38383

### Source

ToetsingOnline

### Brief title

FU-IVO

### 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:** boys, follow up, obstruction, urethra

## Outcome measures

### Primary outcome

IPSS, urinary tract infections episodes, incontinence episodes, uroflowmetry, post void residual

### Secondary outcome

Micturition diary, retrograde ejaculation, coping style

## Study description

### Background summary

Transurethral resection of an infravesical obstruction in boys is frequently performed in this hospital, about 200 times a year. Some patients have evident narrowing of the urethra due to posterior urethral valves or bladder neck hypertrophy, among other causes, while others have much more subtle abnormalities. The long term outcome and complications of severe infravesical obstruction are described in literature [1-5] However, results of treatment of more subtle abnormalities is less well known.

Transurethral resection at young age may lead to complications, e.g. urethral stricture. In adults retrograde ejaculation always occurs after bladder neck incision, in children this is not known.

LUTS, incontinence en recurrent UTI\*s, in combination with a urological intervention at young age, may affect quality of life or coping style. Coping style is the way a person reacts on problems in daily life. Coping style may affect quality of life outcomes.

### Study objective

The goal of this study is to investigate the long term results after transurethral treatment of infravesical obstruction in boys with respect to LUTS, incontinence, urinary tract infections, coping style and quality of life, and possible complications of early transurethral treatment.

## Study design

This is an observational cohort study using questionnaires and a non-invasive bladdertest

## Study burden and risks

Three questionnaires, a micturition diary (one day); non-invasive bladdertest at the outpatient clinic

## Contacts

### Public

Universitair Medisch Centrum Utrecht

heidelberglaan 100  
3584 cx utrecht  
NL

### Scientific

Universitair Medisch Centrum Utrecht

heidelberglaan 100  
3584 cx utrecht  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Male sex  
Age > 18 years  
Transurethral treatment of infravesical obstruction between January 1986 and December 2010  
Willing and able to participate in the study

- Signed informed consent

## Exclusion criteria

Neurogenic bladder disorder  
Congenital anomaly of the penis, like hypospadias or epispadias

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 26-10-2011

Enrollment: 300

Type: Actual

## Ethics review

Approved WMO  
Date: 24-06-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO  
Date: 13-03-2012

Application type:

Amendment

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	NL35634.041.11