

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urethral disorders (excl calculi)
Study type	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

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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