Long-term complications resulting from temporary indwelling urinary catheters in boys. A pilot study.

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The aim of this study is to evaluate the: 1) prevalence of structural (urethral strictures) and 2) functional urethral complications (LUTS, abnormal uroflow characteristics and increased post void residual (PVR) volume) in boys post IUC placement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON55225

Source
ToetsingOnline

Brief title
FOMUCAT study (FOllow Me Urinary CATheter)

Condition

- Urinary tract signs and symptoms

Synonym
urethral strictures; narrowing of the urethra

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, complications, indwelling urinary catheter, urethral strictures

Outcome measures

Primary outcome

In boys *18 years old * three months post IUC placement:

1. The prevalence of structural urethral complications:

1.1. Urethral strictures.

2. The prevalence of functional urethral and bladder complications:

2.1. LUTS.

2.2. Abnormal uroflow characteristics.

2.3. Increased post void residual (PVR) volume.

Secondary outcome

In boys *18 years old * three months post IUC placement:

1. The risk factors of developing urethral strictures and LUTS.

2. The characteristics of urethral strictures and LUTS.

Study description

Background summary

In adult patients the repoted incidence of urethral strictures or erosion post placement of an indwelling urinary catheters (IUC) is 3.4%. In females urethral strictures are reported to be rare. In children the long-term complications of IUC have been studied scarcely, whereas we hypothesise they may experience an increased risk. Additionally, lower urinary tract symptoms (LUTS) in children may remain unrecognized or not directly associated with a previous IUC placement.

Study objective

The aim of this study is to evaluate the:
1) prevalence of structural (urethral strictures) and
2) functional urethral complications (LUTS, abnormal uroflow characteristics and increased post void residual (PVR) volume) in boys post IUC placement.

Study design

Historic cohort pilot study

Study burden and risks

The proposed study was evaluated as carrying negligible risk with minimal burden for the patient.
This is a group-related study, since the long-term sequela of IUC in children have not yet been systematically investigated.

Measurements:

1) Patients and parents/legal guardians will complete the (p)VSSES questionnaire, which comprises 14 questions on micturition.
2) One visit of 1-4 hours at the out patient department (or during planned visit):
2.1) An uroflow assessment, which is a non-invasive investigation of <5 minutes similar as voiding on a normal toilet.
2.2) An abdominal Bladderscan ultrasound (non-invasive) of <5 minutes.
3) Patients will complete a two day bladder diary
4) Patients with abnormal results based on the aforementioned investigations, will be invited for and benefit from an additional urological investigation at the discretion of a pediatric urologist, which will take place as part of regular patient care. However, no invasive procedures will be executed for study purpose only.

Contacts

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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

Sex: male,
Age at placement of the indwelling urinary catheter (IUC): gestational age *37 weeks - *18 years,
Age at follow up: *5 - *19 years,
Cognitive development: no evidence of mental retardation,
Duration of IUC: *24 hours,
Date of IUC placement: *01-01-2016
Time of follow up: *3 months post IUC removal,
Language: Child and at least 1 parent / caregiver have a sufficient mastery of the Dutch language (verbal and written)

Exclusion criteria

Known existing anatomical abnormalities of the urinary tract, previous urological surgery (including circumcision and hypospadias), neurogenic disease and history of pelvis fracture, since these children already experience an increased risk of developing structural urethral complications. Declined informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL74398.018.20