Het toetsen van een vragenlijst voor kinderen met plasproblemen in het Nederlands.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21741

Source
NTR

Brief title
Vancouver SSDES validation in Dutch

Health condition

Dysfunctional voiding.

Sponsors and support

Primary sponsor: Erasmus MC, Dept. Urology
Source(s) of monetary or material Support: Not applicable.

Intervention

Outcome measures

Primary outcome

Internal consistency is the main study endpoint. Total scores of the patient and control group will be used to determine this endpoint.

Secondary outcome

For the following secondary endpoint scores from patient and control group will be used:

• Construct validity

For the following secondary endpoints scores from the patient group will be used:

• Reproducibility

• Content validity

• Responsiveness

• Interpretability

Study description

Background summary

Children with dysfunctional voiding suffer from both urinary and bowel symptoms. A scoring system to quantify these symptoms and detect improvement is the Vancouver symptom score for dysfunctional elimination syndrome. This questionnaire enables us to assess the effectiveness of treatment in children with dysfunctional voiding.

Children with dysfunctional voiding are asked to fill out the Vancouver SSDES at three time-points. They are also asked to fill out an extra questionnaire at two time-points, in order to validate the Vancouver SSDES. They will also be asked to fill out a voiding diary for two days at two time points, which is part of standard care. Children in the control group are asked to fill out the two questionnaires only once. No extra outpatient visit is required. The questions in the questionnaires are similar to the medical history during an outpatient visit. The burden is therefore minimal for these children. Participation in this study will not influence patient treatment.

Study objective

To validate the Vancouver Symptom Score for Dysfunctional Elimination Syndrome in Dutch.

Study design

Patient group: baseline, 1 week after baseline, and after treatment.

Control group: baseline only

Intervention

Not applicable: study is observational.

Contacts

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Eligibility criteria

Inclusion criteria

Patient group:

• Male or female children aged 6 – 16 years

• Has DV

• Child and at least one parent fluent in the Dutch language

• Signed informed consent

Control group:

• Male or female children aged 6 – 16 years

• Has no urinary tract symptoms

• Child and at least one parent fluent in the Dutch language

• Signed informed consent

Exclusion criteria

• Has a neurogenic disease

• Has anatomic abnormalities of the urinary tract

• Has received previous urological surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-08-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion Date:	02-07-2014
Application type:	First submission

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
NTR-new	NL4529
NTR-old	NTR4664
Other	METC 2014-290 : OZBS62.14018

Study results