Veranderingen in plaspatroon en kwaliteit van leven bij kinderen met plasproblemen die een behandeling met Botox krijgen.

No registrations found.

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

Summary

ID

NL-OMON23220

Source
NTR

Brief title
Change in voiding pattern after BoNT-A

Health condition

Dysfunctional voiding.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

PVR, defined as volume of residual urine in the bladder after voluntary voiding determined

through ultrasound, after treatment at predetermined time points compared to baseline.

Secondary outcome

Results after treatment compared to baseline determined at predetermined time points:

• Incontinence episodes per day derived from the voiding diary

• 24 hour frequency derived from the voiding diary

• Number of UTIs: clinical symptoms (pollakiuria, dysuria) combined with a positive dipstick for leucocytes or a positive urine culture

• Peak flow in ml/s derived from uroflowmetry

• Scores derived from the PINQ and Vancouver SSDES questionnaires

• Duration of improvement of voiding pattern and quality of life

Study description

Background summary

Dysfunctional voiding (DV) is a term used for nonneurogenic increased urethral sphincter or pelvic floor muscle activity during voluntary voiding. The result is a lack of coordination between the detrusor muscle and the urethral sphincter. This results in either symptoms of urinary incontinence (UI), urinary tract infections (UTIs), or high post-void residual (PVR). A substantial group of children with DV, 10-40%, remains therapy-refractory. This group of children currently receives BoNT-A injections in the external urethral sphincter at Erasmus MC - Sophia as standard care. In a retrospective analysis performed by the investigators of the current protocol BoNT-A treatment has shown to be an effective and safe treatment option.

Children will receive BoNT-A treatment as standard care. Changes in voiding pattern and quality of life will be determined at predetermined time points based on uroflowmetry, dipstick analysis, PVR determination, voiding diaries, and questionnaires.

This patient group has an average of 6 outpatient visits per year as part of standard care. During the last study visit they will perform an extra uroflowmetry and keep a voiding diary for two days similar to the other five outpatient visits. Patients will be asked to fill out two

questionnaires, which are not part of standard care, at seven time points. They are asked to keep a voiding diary for two days at seven time points, including for telephone contact. This is one extra time compared to standard care.

Study objective

To assess the change in voiding pattern and quality of life in children who receive BoNT-A treatment in a prospective setting.

Study design

Baseline, 2 weeks after baseline, week 0, week 2, week 6, 3 months, 6 months, 9 months, 12 months.

Intervention

Not applicable: study is observational.

Contacts

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Eligibility criteria

Inclusion criteria

• Male or female children aged 5-12 years

• Has therapy-refractory DV and the next step in treatment is BoNT-A injection

• Has received a minimum of five sessions of urotherapy

• Has received a minimum of two sessions of pelvic floor muscle physical therapy

• Signed informed consent

Exclusion criteria

• Has anatomic abnormalities of the urinary tract

• Patients who have received additional treatment:

o BoNT-A injections in the detrusor muscle

o Appendicovesicostomy

o Bladder augmentation

• Has a neurogenic disorder

• Has a neuromuscular disorder

• Has a psychological disorder

• Uses products that influence neuromuscular transmission

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2014
Enrollment:	30
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	NL4530
NTR-old	NTR4665
Other	METC 2014-223 : OZBS62.14009

Study results