Change in voiding pattern and quality of life in children with dysfunctional voiding who receive BoNT-A treatment: a prospective study.

Published: 11-06-2014
Last updated: 21-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON40770

Source
ToetsingOnline

Brief title
Change in voiding pattern after BoNT-A

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Dysfunctional voiding, urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Dyspunctional voiding, Quality of life, Voiding pattern

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.

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

A prospective observational cohort study.

Study burden and risks

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.

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

* 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-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2015
Enrollment:	33
Type:	Actual

Ethics review

Approved WMO

Date:	11-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48932.078.14