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

Gepubliceerd: 02-07-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23220

Bron
NTR

Verkorte titel
Change in voiding pattern after BoNT-A

Aandoening

Dysfunctional voiding.

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Not applicable: study is observational.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2014
Aantal proefpersonen:	30

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-07-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4530
NTR-old	NTR4665
Ander register	METC 2014-223 : OZBS62.14009

Resultaten