Dysfunctional voiding: exploring disease transition from childhood to adulthood

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21136

Source
NTR

Brief title
Dysfunctional voiding:

Health condition

Dysfunctional voiding (DV) is a condition characterized by an impaired relaxation of the pelvic floor musculature during voiding, with a poorly understood etiology. In children and adults it is known to cause residual urine after voiding with subsequent UTI’s, and daytime urinary incontinence (DUI) due to an impaired sensation for the filling state of the bladder.

Sponsors and support

Primary sponsor: UMCU
Source(s) of monetary or material Support: UMCU

Intervention

Outcome measures

Primary outcome

Persisting or relapse of DV from baseline and/or after conservative treatment to adulthood, expressed as the percentage of adults with DV. DV is herein determined according to ICS

criteria as the presence of a staccato and/or intermittent urinary flow

Secondary outcome

- Daytime urinary incontinence in days per week, defined as any form of involuntary leakage of urine.
- Post-void residual defined as the volume of urine in milliliter left in the bladder at the end of micturition.
- Urinary tract infections , defined as a bacteriuria, with or without fever, with need for antibiotic treatment in the last six months.
- Conservative treatment success, as described in the study of Klijn et al. (previous mentioned) and quantified according to the ICCS criteria.

Study description

Background summary

SUMMARY

Rationale & objective:
Dysfunctional voiding (DV) is a condition characterized by an impaired relaxation of the pelvic floor musculature during voiding. Both the International Continence Society (ICS) as the International Children's Continence Society (ICCS) use equivalent definitions, wherein the existence of a staccato/intermittent urinary flow is central.
Up to date it is however still not clarified if adult cases are new-onset presentations of DV or persistent childhood complaints. It is unknown if there is a continuation of DV from childhood to adulthood. The aim of this study is therefore to explore the development of DV from childhood to adulthood, in order to improve our transitional care and to avoid repeated invasive examination in adults with childhood DV .

Study design:
This is a cohort-study with cross-sectional follow-up in female adults (>18 years) who were treated for childhood DV in the Wilhelmina Children's Hospital. After chart study on existing data regarding DV diagnostic criteria and comorbid symptomatology at baseline and after conservative treatment in childhood, all participants will be invited for a uroflowmetry with post-void residual assessment at the outpatient clinic of the UMC Utrecht and will receive digitally a combined version of the International Consultation on Incontinence modular Questionnaire – Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and International Consultation on Incontinence modular Questionnaire – Urinary Incontinence (ICIQ-UI) questionnaires regarding lower urinary tract symptoms (LUTS) with additional questions on the presence of urinary tract infections (UTI's).

Study population:
Female adults (>18 years) who were treated for childhood DV in the Wilhelmina children's

hospital and completed the follow-up in the RCT of Klijn et al../ UWOK 830-999-99-23.

Main study parameters/endpoints:
Persisting or relapse of DV from baseline and/or after treatment to adulthood. DV is herein defined according to the ICS and ICCS standardization paper as a bladder outlet problem, characterized by contractions of the peri-urethral striated muscles during voiding, which consequently demonstrates a staccato or intermittent uroflow pattern on uroflowmetry with or without residual urine after voiding in neurologically normal individuals
Nature and extent of the burden associated with participation, benefit and group relatedness:
Study-related risks
The risks associated with participation are negligible. Uroflowmetry with post-void residual assessment is a non-invasive procedure, without adverse events.

Study-related benefits
The outcome of the study could improve the transitional care of young-adults with DV and help to avoid repeated invasive examination in adults with childhood DV. Furthermore, outcomes of this study may improve information about future expectations for children with DV and their parents.

Having an existing cohort with a large number of neurologically normal, conservatively treated girls with DV offers herein a unique opportunity to objectively asses the transition of DV, without the occurrence of recall-bias.

Study objective

The aim of our present study is therefore to explore the development of DV from childhood to adulthood in order to improve our transitional care and to avoid repeated invasive examination in adults with childhood DV

Study design

Once by a questionnaire and a visit to the outpatient clinic, UMC Utrecht.

Questionaire:
Participants will digitally receive a questionaire: a combined version of the International Consultation on Incontinence modular Questionnaire – Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and International Consultation on Incontinence modular Questionnaire – Urinary Incontinence (ICIQ-UI) questionnaires regarding LUTS, with additional questions on the current presence of UTI’s,

Flowmetry &Ultrasound:
During a 1 visit to our clinic the particitpants will undergo once a uroflowmetry with post-void residual assessment by ultrasonography. All test will be performed at the same visit.

A uroflowmetry is a simple and noninvasive test. It is the graphical recording of the urinary stream, which gives information on voided volume, flow time, velocity at start of the stream, maximal flowrate (expressed in mL/s), and flow pattern. Flow curve shape provides accurate

information on voiding and are automatically assessed with Contouro to avoid inter-rater variability. DV typically comes with a staccato or interrupted flow pattern resulting in residual urine.
Therefore after uroflowmetry an transabdominal ultrasound will be done to assess the existence of residual urine in the bladder.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in the study, a subject must meet all of the following criteria:

1. Female gender
2. Diagnosed with DV in childhood, defined according to the ICCS standardisation paper (3).
3. Completed follow-up (assessment of relief from infections and incontinence at 12 months after initial randomization) in the RCT of Klijn et al .
Klijn AJ, Uiterwaal CSPM, Vijverberg MAW, Winkler PLH, Dik P, de Jong TPVM. Home Uroflowmetry Biofeedback in Behavioral Training for Dysfunctional Voiding in School-Age Children: A Randomized Controlled Study. J Urol. 2006;175(6):2263–8.

Exclusion criteria

1.Neurological bladder disorders

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):	01-06-2021
Enrollment:	130
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9460
CCMO	NL.7639104121

Study results