Home bladder pressure measurement

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23230

Source
NTR

Brief title
Home bladder pressure measurement

Health condition

Meningomyelocele

Sponsors and support

Primary sponsor: Erasmus MC, Dept. Urology
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Reduction in unscheduled hospital visits due to bladder and kidney problems.

Secondary outcome

- Preservation of bladder and renal function and quality of life.

- Patient compliance to medication and CIC.

- Incidence and severity of bladder dysfunction related symptoms (incontinence and overactivity related discomfort).

- Time of detection and frequency of tethered cord or other new neurological damage.

- Time of detection and frequency of urinary tract infection (UTI).

- Anticholinergic application form.

- Actual dose of medication, determined from the answers on the questionnaires and answers on the specific question on use of medication in the webtool.

- Actual CIC frequency.

- Patient satisfaction with treatment.

- Workload treatment team.

- Visits to website (indicator for motivation).

Study description

Background summary

Children with neurogenic bladder/sphincter dysfunction (BSD) of which the main diagnosis is myelomeningocele (MMC) need life-long treatment by a multidisciplinary team to prevent loss of renal function, urinary tract infection (UTI) and incontinence. Currently the standard approach is to prevent high bladder pressure and bladder overactivity with anticholinergic drugs, to empty the bladder by Clean Intermittent Catheterization (CIC) and, if this option is available, to monitor urinary tract function with yearly video urodynamic studies (VUDS). The medication is administered either oral or intravesical. This approach has had some success but is still suboptimal. Quality of life (QOL) is still reduced by incontinence, many patients are plagued by recurring UTI's, and renal transplantation and even mortality are still end-stages for MMC patients. In view of the serious consequences and the life-long aspect of the disease there is a need to improve the treatment.

The combined treatment with anticholinergics (oral or intravesical) and clean intermittent catheterization (CIC) reduces long term loss of bladder and kidney function in children with bladder overactivity. The clinical results of the combination anticholinergics and CIC in general practice are lower than could be expected on basis of the results obtained in controlled studies due to decreasing patient compliance in the long term. Compliance is defined here as use of medication and application of CIC according to the prescribed dose

and frequency. The application of feedback tools may improve patient compliance and thereby the clinical results obtained with the current treatment of these patients.

We aim to increase patient compliance by extending the existing treatment protocol of (oral or intravesical) anticholinergics plus application of CIC with the addition of bladder pressure measurement performed at home during CIC plus access to an interactive website that provides feedback on the individual situation. This should improve the clinical results, the occurrence of bladder/kidney problems and the quality of life. Consequently it should reduce the number of unscheduled hospital visits due to bladder and kidney problems.

This study is a controlled intervention study. The study population exists of 100 children with Meningomyelocele, who are randomized in 2 groups:

Group 1:

Standard treatment of oral or intravesical anticholinergics and CIC, yearly visits to the outpatient clinic, and yearly quality of life questionnaire, and urine volume twice a month, access to a website with general information on their disease and its treatment. The choice of anticholinergic application form is free.

Group 2:

Standard treatment of oral or intravesical anticholinergics and CIC, yearly visits to the outpatient clinic, yearly quality of life questionnaire, and measurement of bladder pressure at home by using an extended catheter placed along a vertical ruler and urine volume twice a month. The patients (or caregivers) enter the data on a secured website that provides them feedback on their current situation and an overview of their historic situation. The website is entered with a username and password. Patient name, patient number, address, and the name of the treating doctor are not in the online database. The choice of anticholinergic application form is free.

Burden to group 1 (control group):

- A 3 year participation in the study.

- Measurement of urine volume during the first catheterization of the day twice a month.

- Filling out a questionnaire on quality of life once a year (4 total).

Burden to group 2 (test group):

- A 3 year participation in the study.

- Measurement of bladder pressure and urine volume during the first catheterization twice a month and entering the data on the interactive website.

- Filling out a questionnaire on quality of life once a year (4 total).

Overall the burden and risks associated with participation are for both groups considered to be minimal.

Study objective

Addition of home measurement of bladder pressure and access to an interactive website reduces unscheduled hospital visits due to bladder and kidney problems.

Study design

Screen visit, year 1, year 2, and year 3.

Intervention

Group 1:

Standard treatment of oral or intravesical anticholinergics and CIC, yearly visits to the outpatient clinic, and yearly quality of life questionnaire, and urine volume twice a month, access to a website with general information on their disease and its treatment. The choice of anticholinergic application form is free.

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Standard treatment of oral or intravesical anticholinergics and CIC, yearly visits to the outpatient clinic, yearly quality of life questionnaire, and measurement of bladder pressure at home by using an extended catheter placed along a vertical ruler and urine volume twice a month. The patients (or caregivers) enter the data on a secured website that provides them feedback on their current situation and an overview of their historic situation. The website is entered with a username and password. Patient name, patient number, address, and the

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Eligibility criteria

Inclusion criteria

- Children 0-18 years

- Already treated at our center with CIC and anticholinergics or new patients at our center who need CIC and anticholinergic treatment

Exclusion criteria

- Non-neurogenic BSD (e.g. urethral valves)

- Neurogenic bladder after bladder augmentation

- Inability of patient/ caregivers to understand the instructions on how to perform CIC

- Inability of patient/ caregivers to understand the instructions on the home bladder pressure measurements

- Inability of patient/caregivers to understand the instructions on application of the anticholinergics intravesical

- Inability of patient/ caregivers to understand the instructions on the use of the website.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39539
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3858
NTR-old	NTR4101
CCMO	NL42026.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39539

Study results

Summary results
N/A