Neurogenic bladder in children: use of feed-back tools during standard treatment with anticholinergics.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract disorders congenital
Study type	Interventional

Summary

ID

NL-OMON39539

Source
ToetsingOnline

Brief title
Home bladder pressure measurement.

Condition

- Renal and urinary tract disorders congenital
- Spinal cord and nerve root disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
bladder sphincter disorder, Neurogenic bladder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: * Anticholinergics and CIC, * Feedback tools (interactive website), * Home Bladder pressure measurement, * Neurogenic bladder in children

Outcome measures

Primary outcome

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

Secondary outcome

- Preservation of bladder and renal function and quelity 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.

Study objective

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.

Study design

Controlled intervention study.

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.

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.

Study burden and risks

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.

The study is group related as the study can only be performed in this patient group.

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

* Children 0-18 years
* Already treated at our centre with CIC and anticholinergics or new patients at our centre 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
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2013
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

ID: 23230
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42026.078.12
OMON	NL-OMON23230