Home bladder pressure measurement

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23230

Bron
NTR

Verkorte titel
Home bladder pressure measurement

Aandoening

Meningomyelocele

Ondersteuning

Primaire sponsor: Erasmus MC, Dept. Urology
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39539
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A