

Cognitive bladder training versus rectal wash-out training for girls with dysfunctional voiding and constipation.

No registrations found.

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

Summary

ID

NL-OMON26475

Source

NTR

Brief title

UFO2

Health condition

1. Dysfunctional voiding;
2. recurrent urinary tract infections;
3. constipation.

(NLD: urineweginfecties, obstipatie).

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Wilhelmina Kinderziekenhuis, Pediatric Renal Center

Source(s) of monetary or material Support: Nuts/OHRA

Intervention

Outcome measures

Primary outcome

The primary outcome parameter of the study is the absence of urinary tract infections. This is defined as having had no urinary tract infections in the last 6 months of study observation.

Secondary outcome

Secondary outcome measures are:

absence of urinary incontinence in the last 6 months of study observation and recovery of the normal rectal sensation.

Study description

Background summary

Non-neurogenic bladder/sphincter dysfunction (NNBSD) is characterized by impaired relaxation of the pelvic floor during voiding and defecation, with predominate occurrence in girls. It results mandatorily into residual urine after voiding with subsequent symptoms of urinary tract infections (UTI's), urinary incontinence and constipation with fecal incontinence. Patients also have an impaired sensation of the filling state of both the bladder and the rectum which leads to rectal overdistension without urge to defecate. Untreated, the girls are at risk for chronic renal failure and for life-long pelvic floor problems. Over the years, treatment has been focussed on the learning of proper bladder emptying combined with standard oral treatment of constipation. Intractable NNBSD in general hospitals requires referral to larger (academic) hospitals where specialized treatment is available. There, outpatient treatment consists of cognitive bladder training, antibiotics and laxatives, toileting instruction, with a few visits to the outpatient clinic and weekly telephone calls for follow-up. This will cure only 50% of patients, while at the same time cognitive bladder training is a highly specialized intensive and therefore expensive treatment. Importantly, the nature of cognitive bladder training makes it available only to patients of age 6 and higher, while in the majority of patients symptoms evolve from about the age of 4. The younger patients currently have to do with antibiotics, laxatives and instructions, and have to wait till age 6 for cognitive bladder training. If the current specialized outpatient treatment is ineffective, further hospitalized cognitive and biofeedback treatment will be successful in the majority of the remaining 50% but at high economic costs. It is pivotal that higher success rates are achieved in the outpatient phase. In children that failed to be cured from UTI's it has become a plausible suggestion that the persistent rectal distension with fecal compaction is the major cause for treatment failure. Therefore, temporary retrograde rectal wash-out might diminish rectal distension and result in recovery of normal rectal sensation. Here we propose to study the effects of a temporary rectal wash out program as an alternative for outpatient cognitive bladder training. Rectal wash-out is a standard intervention in spina

bifida patients with, in our department, 3700 patient years of experience without complications. Moreover, in the last years, we have done rectal wash-out in 72 cases with intractable NNBSD with excellent satisfaction for both the patients and the parents.

Study objective

An intensive rectal wash-out program for constipated girls with NNBSD is as effective in curing recurrent urinary tract infections as cognitive bladder training in standard outpatient treatment.

Study design

N/A

Intervention

1. Cognitive bladder training;
2. Rectal wash-out training.

ad 1. the children will receive antibiotic medication, oral laxatives and training by a urotherapist. This consists of outpatient visits for elaborate instruction about voiding and defecation patterns, toileting posture, diet and fluid intake. Children are also taught about proper recognition of bladder signals, and timing and ways of urination. Weekly telephone contact between the urotherapist and the patient is used for motivation and control. After 3 months a second outpatient visit will take place in which a formal evaluation of bladder-emptying and of constipation is done. Antibiotic prophylaxis is then terminated. The following 6 months patients are observed for UTI's, incontinence and constipation.

Ad 2. these patients will receive antibiotic medication, oral laxatives and physician instructions on toilet use. Additionally, they get instructions on a rectal washout program with water that will be used at home during a total period of 3 months. Wash-out enemas will be given daily for 1 week, 3 times a week for 6 weeks, 2 times a week for 5 weeks. Enemas will be administered by the parents after instructions by a nurse. After 3 months a second outpatient visit will take place in which a formal evaluation of bladder-emptying and of constipation is done. Antibiotic prophylaxis is then terminated. The following 6 months patients are observed for UTI's, incontinence and constipation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female gender;
2. age between 6 and 12 years;
3. Non-Neurogenic Bladder/Sphincter Dysfunction (NNBSD) with recurrent Urinary Tract Infections (UTI) and constipation as shown by clinical evaluation, urodynamics, and ultrasound;
4. with or without urinary incontinence.

Exclusion criteria

Congenital anomalies of the lower urinary tract except for vesico-ureteral reflux; and previous surgery of the urinary tracts except for surgery concerning vesico-ureteral reflux and correction of meatal stenosis.

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-03-2008 |
| Enrollment: | 120 |
| Type: | Anticipated |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 15-01-2008 |
| Application type: | First submission |

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 | NL1138 |
| NTR-old | NTR1180 |
| Other | : incomplete |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Study results

Summary results

R. Chrzan e.a; Rectal wash-out program for treatment of UTI's in children with Dysfunctional voiding and constipation. Urology, 2007, in press.