Cognitive bladder training versus rectal washout training for girls with recurrent urinary tract infections and urinary incontinence

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Research question: is primary aggressive treatment of constipation with rectal wash-out in girls with NNBSD at least equally effective as usual care?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31588

Source
ToetsingOnline

Brief title
Dysfunctional elimination treatment for urinary tract infections

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
dysfunctional voiding, non-neurogenic bladder/sphincter dyscoordination

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: constipation, Dysfunctional voiding, recurrent urinary tract infections

Outcome measures

Primary outcome

Cure of UTIs, 6 months after stop of chemoprophylaxis, will be the primary goal

of treatment.

Secondary outcome

Cure of urinary incontinence, when relevant, is the second goal of treatment,

recovery of normal rectal function and relief of constipation is the third.

Study description

Background summary

Girls with non-neurogenic bladder/sphincter dysfunction (NNBSD) have impaired relaxation of the pelvic floor during voiding and defecation. This results mandatorily into residual urine after voiding with subsequent urinary tract infections (UTIs), urinary incontinence, constipation and fecal soiling.
Patients also suffer from an impaired feeling of the filling state of both the bladder and the rectum which leads to rectal overdistension without urge to defecate. NNBSD is socially important as 7-10% of all girls have complaints in this field and 40% of these have vesico-ureteric reflux as well that can lead to complicated UTIs with renal scarring. Untreated, the girls are at risk for chronic renal failure and for life-long pelvic floor problems. When treated properly renal function is secured and pelvic floor dysfunction at later age is prevented.
Over the years, treatment has been focussed on the learning of proper bladder emptying combined with standard oral treatment of constipation. In the group of children that failed to be cured from UTIs it has become a plausible suggestion that the persistent rectal distension with fecal compaction is the major cause for treatment failure and that only active treatment of the distended rectum can control the disease. Temporary retrograde rectal wash-out with water is expected to restore proper feeling of rectal filling and proper emptying of the distended rectum with subsequent relief of the lower urinary tract problems.

Literature provides sufficient clues to support this suggestion.

Study objective

Research question: is primary aggressive treatment of constipation with rectal wash-out in girls with NNBSD at least equally effective as usual care?

Study design

Girls aged 6 to 12 years with NNBSD, afdter 3 months of standard outpatient treatment, will be randomly allocated to receive either standard outpatient cognitive bladder training by a urotherapist combined with antibiotic prophylaxis and oral laxatives, or to the standard medical outpatient treatment combined with a 3 months episode of rectal wash-outs with water at home. The study will take 24 months for completion. The ultimate goal is to derive at an alternative treatment for NNBSD that can be applied at a younger age and is probably cheaper than usual care.

Intervention

3 months standard outpatient treatment
3 months study intervention 1 or 2 with continuation of medication.
After 6 months chemoprophylaxis is stopped.

Study burden and risks

Burden is comparable with the current treament of the condition.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

recurrent urinary tract infections, NNBSD, residual urine after voiding >10% of expected bladder capacity for age, possibly urinary incontinence, persistent rectal constipation after at least 3 months oral laxative therapy. School maturity.

Exclusion criteria

congenital malformations of the urinary tract other then vesico-ureteral reflux, earlier surgery on the lower urinary tract other then surgery for reflux or meatal stenosis, impossible communication in Dutch or English.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2008
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	colonic irrigation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-02-2007
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-07-2008
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL13337.041.06