Assessment of asymmetrical innervation of the right and left m. puborectalis as a possible cause of idiopathic incontinence, by using concentric needle electrodes in an electromyography investigation of the pelvic floor muscles.

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Is it possible to make a discrimination in muscle activity between the right and left puborectalis muscle by using concentric needle electrodes in an electromyography investigation of the pelvic floor muscles?When a asymmetry is found, what can be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON38239

Source ToetsingOnline

Brief title An asymmetrical innervated sphincter is insufficient.

Condition

Muscle disorders

Synonym Denervation, loss of nerve supply

Research involving

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Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht Source(s) of monetary or material Support: continentie stichting

Intervention

Keyword: concentric neelde electrodes, EMG, incontinence, puborectalis muscle

Outcome measures

Primary outcome

There will be tonic activity in the puborectalis muscle when the patient is sedated (low-threshold MUPs), in contrast to skeletal muscles. A difference in muscle activity is demonstrated by the motor unit potential (MUP) count. Besides that there is a prolonged insertion activity in denervated muscles.

Secondary outcome

The MUP parameters will be compared with the normative values as described in literature. MUP parameters are: amplitude, duration, area, thickness, size index, phases, turns and spike duration. In denervated and reinnervated muscles these values are abnormal. In reinnervated muscles a prolonged wave form of the MUP is seen together with instability of the MUP. After some time the duration of the MUP reverts towards normal while the MUP amplitude increases. Furthermore, it is important to observe whether there is abnormal spontaneous activity on one or both muscles, because this is an indication for a pathology.

Study description

Background summary

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The overall prevalence of children (6-10 years) with incontinence problems is 6-9%. These problems have a deep impact on the social life of a child. It is not only a problem for the family, but also at school it is a problem. This can result in misunderstanding. There are several causes for incontinence, therefore it is important to have sufficient knowledge of the anatomy and pathophysiology. It is important to have a good diagnosis, only this will lead to a successful treatment. When a wrong diagnosis is provided, treatment will not be successful and this will result in frustrations.

With the current diagnostic methods it is not always possible to provide a good diagnosis. In this study an EMG investigation of the puborectalis muscle will be performed with concentric needle electrodes. In general, this is performed with surface electrodes, but then it will not be able to assess the activity of a single muscle. This muscle will be measured to assess whether there is a difference in innervation between the right and left muscle. The hypothesis is that there is an asymmetry in innervation of the right and left puborectalis muscle in patients with idiopathic incontinence problems. These patients have an overactive bladder or dysfunctional voiding and are not suspected for having a neuropathology, but the hope is to find a neurologic substrate for their problems.

Study objective

Is it possible to make a discrimination in muscle activity between the right and left puborectalis muscle by using concentric needle electrodes in an electromyography investigation of the pelvic floor muscles?

When a asymmetry is found, what can be said about denervation and reinnervation based on the MUP parameters?

Study design

The study design is an observational cross-sectional survey, in which the subjects are measured once.

The measurements will take 5 to 10 minutes preceding the cystoscopy. The investigation will be performed in the Wilhelmina Pediatric Hospital in Utrecht.

Study burden and risks

The study is a group-based investigation, that means that the investigation can only be performed with the described study population. The problems affecting this group of patients and the causes are different in adults for example. The investigation has not directly therapeutic means as described previously.

The risks and burden for the patient can be considered minimal. The patient could have a small hematoma in the pelvic floor with temporary a painful

sensation. The pediatric urologists that will be involved in the investigation have years of surgical experience, thus the risks will be low.

Contacts

Public

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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

The subjects have idiopathic urinary or faecal incontinence problems. The subjects have an overactive bladder or dysfunctionel voiding. The subjects are in the age of 5 to 17 years. The subjects need a cystoscopy.

Exclusion criteria

When subjects have had bladder neck surgery.

When subjects have severe congenital anomalies of bladder neck and urethra (epispadias, ectopic ureteroceles, exstrofy).

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-08-2012
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO	
Date:	15-
Application type:	Firs
Review commission:	ME

15-06-2012 First submission 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 CCMO **ID** NL37507.041.11