The central cause of overactive bladder, a pilot study

Published: 24-11-2008
Last updated: 10-05-2024

The objective of this study is to proof the presence of lesions in the brain of patients with overactive bladder and urge-incontinence (OAB wet) as a central cause of this disorder. This survey is a pilot investigation for a larger study on the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31796

Source
ToetsingOnline

Brief title
pilot study MRI overactive bladder

Condition

- Neurological disorders NEC
- Urinary tract signs and symptoms

Synonym
urge-incontinence, wet overactive bladder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, overactive bladder, urge-incontinence, white matter lesions

Outcome measures

Primary outcome

Primary objective is to investigate by means of MRI-scanning whether severe OAB wet patients suffer more from white matter lesions in the regions belonging to the limbic and emotional system and the prefrontal cortex or in the region of the pathways from these brain regions to the PAG in comparison to the volunteers.

Secondary outcome

Secondary objective is to test the study design we are planning to use in a major MRI study on the central cause of OAB dry and wet, in which we will correlate the severity of white matter lesions to the severity of OAB dry and wet.

Study description

Background summary

Micturition is a complex process with interaction between the central and peripheral nervous system on one hand and the bladder and urethra on the other hand. It is a well balanced co-ordination between contraction of the detrusor and relaxation of the urethral sphincter. This process, according to Holstege, is controlled by a spinal-brainstem-spinal reflex system in which information about bladder filling is continuously sent from the bladder, via the sacral cord to the central part of the periaqueductal gray (PAG) in the midbrain. Based on the bladder filling rate, certain cell groups in the lateral PAG can activate the pontine micturition center (PMC). However, the PAG, in deciding whether or not to activate the PMC, is strongly influenced by different regions belonging to the limbic or emotional system, as well as by regions in the prefrontal and orbitofronral cortex. All these regions continuously evaluate

the safety of the environment. In urge urinary incontinence these limbic system or prefrontal cortical regions or their pathways to the PAG are dysfunctional as a result of many small lesions caused by vascular or neurodegenerative diseases.
At present most treatment modalities for OAB have their target in the bladder wall. Antimuscarinic agents, the most frequently used therapy, reduce bladder tone and increase bladder capacity during the filling phase. Other treatments are behavioural therapy, pelvic floor muscle therapy, neuromodulation and surgery. If the hypothesis that OAB in general is not a disease of the bladder itself but of vascular or neurodegenerative brain disease is true, OAB should be considered as a neurological disease that needs different therapies than presently given.

Study objective

The objective of this study is to proof the presence of lesions in the brain of patients with overactive bladder and urge-incontinence (OAB wet) as a central cause of this disorder. This survey is a pilot investigation for a larger study on the central cause of overactive bladder and urge-incontinence.

Study design

An observational pilot study in 5 women and 5 men with overactive bladder and urge-incontinence (OAB wet) and 5 volunteers (male/female) without any sign of OAB or incontinence. In this study we will look by means of MRI scanning for white matter lesions in the brain.

Study burden and risks

Patients and volunteers have to visit the outpatient clinic for an interview.
At home they have to fill in three questionnaires, and record a voiding diary during 3 days. At a second visit a MRI scan will be made. Intravenous contrast solution will not be used. Scanning time will be approximately 30 minutes. We expect to find white matter lesions. In case of unsuspected disorders found on MRI scanning such as meningiomas or aneurysms which need further evaluation and treatment, the general practitioner will be informed.
SAFETY
The risk for the participants is very low. There is no medication involved in the protocol. All investigations are non-invasive.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

overactive bladder with severe urge-incontinence

Exclusion criteria

uterovaginal prolaps POP-Q stage II of more (women)
beningn prostate hypertrophy (men)
dementiia
cerebrovascular accident in medical history
contraindication for MRI

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL20883.042.07