

The use of functional-MRI in the imaging of the central regulation of micturition in the healthy male and female.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON31388

Source

ToetsingOnline

Brief title

fMRI in imaging of the centers controlling micturition

Condition

- Structural brain disorders
- Urinary tract signs and symptoms

Synonym

incontinence, 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: bladder volume, brainstem, fMRI, micturition

Outcome measures

Primary outcome

Changes in activation of brain structures as a respond to increased bladder volume and micturition.

Secondary outcome

not applicable

Study description

Background summary

Overactive bladder is a condition characterized by urgency, frequency and urge incontinence. A relatively new treatment is to inject Botulinum toxin A in the bladder wall. This appears to be effective and is rapported to reduce complaints in 70-80% of the patients. As yet the precise working mechanism is unclear. One of the theories is that Botulinum toxin A has an effect on the afferent part of the micturition innervation pathway.

The micturition process is coordinated in the brainstem. The pontine micturition center (PMC) causes excitation of parasympathetic bladder motoneurons in the sacral spinal cord. By releasing acetylcholine in the synaptic junction these motoneurons initiate detrusor contraction. The afferent pathway of the micturition control system consists of A δ -fibers, which respond to stretch of the bladder wall. In this way the periaqueductal gray (PAG) in the brainstem is continuously informed about the bladder content. There exist strong connections between various limbic system related brain structures and the PMC, which are believed to be inhibitory. Probably the urge to void is suppressed by the emotional system, until there is an appropriate opportunity to void.

There are two theories concerning the cause of overactive bladder. The first one relies on increased sensitivity of peripheral afferent fibres; the second on lesions in the central pathway described above. Lack of inhibition of the urge signal would mean a constant urge to void, hence the overactive bladder.

Study objective

The eventual aim of the study is to determine the effects of Botulinum toxin injections in the bladder on overactive bladder.

The objective of this initial study is to determine what brainstructures are activated in respond to increasing volumes of the bladder and micturition.

Study design

The study will be prospective as healthy volunteers will undergo a set of fMRI-scans before and after their bladder has been filled using a transurethral catheter and during micturition.

Study burden and risks

The study is performed in healthy subjects who will undergo catheterization and filling of the bladder. This means a minor risk of urinary tract infection. Also they will undergo an fMRI-scan prior to and after filling of the bladder with saline and during micturition. If the contra-indications are taken into account, the MRI has no known side effects or complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

male and female volunteers, 20 to 65 years of age

Exclusion criteria

contra-indications to MRI-scanning, micturition complaints, any neurological disease or intracranial abnormality

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2007

Enrollment: 10

Type: Anticipated

Ethics review

Approved WMO

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
CCMO	NL17250.042.07