Study of brain areas involved in the sensation of bladder filling in healthy females and untreated females with Overactive Bladder (OAB) using fMRI and water pressure urodynamics

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Ethical review	Approved WMO
Status	Completed
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON55567

Source
ToetsingOnline

Brief title
Brain areas involved in bladder filling and contraction.

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Overactive bladder syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bladder contractions, Bladder sensation, Micturition brain centre, Overactive bladder

Outcome measures

Primary outcome

During urodynamic assessments we will measure bladder pressure changes during

the filling phase with water pressure urodynamics during the fMRI study.

Secondary outcome

Secondary goals are to assess the correlation between bladder filling and

subjects* bladder sensations in combination with psychological anxiety and

depression status, measured through Hospital Anxiety and Depression Score

(HADS) questionnaire.

Study description

Background summary

Overactive Bladder syndrome (OAB) is a medical condition with symptoms of urgency, with or without incontinence, usually with frequency and nocturia, with no proven infection or obvious pathology 1. This study will explore the relationship between OAB, obstruction and the micro contractions as well as the brain areas involved in both normal desire to void and urgency, gaining a better understanding of the bladder pathophysiology and in the future allowing better strategy of treatment options for patients suffering from OAB.

Study objective

Main objectives are to identify brain areas involved in sensation of bladder filling through fMRI during urodynamic measurements. Secondary goals are to

assess the correlation between bladder filling and subjects* bladder sensations in combination with psychological anxiety and depression status, measured through Hospital Anxiety and Depression Score (HADS) questionnaire.

Study design

The study aims to identify differences in bladder flling activities between OAB subjects and healthy subjects, using urodynamic assessment and study relevant brain areas involved in urgency sensation using fMRI. Study will be conducted according to open, non-randomized, parallel group design. The study is set up as an exploratory study to use FMRI brain imaging to study the relevant brain areas involved in bladder sensation.

Study burden and risks

Most of the assessments (physical examination, pregnancy test, diary and questionnaires) are all standard for patients with lower urinary tract symptoms and do not pose additional risk. After urodynamic investigation subjects may experience a burning sensation during urination. The risk of developing urinary tract infection is very low. Regarding the fMRI, certified users will always stay below the limits for radiofrequency and magnetic resonance, making 7T scanning harmless. 5% may experience vertigo or nausea while entering the scanner. Slowing the subject*s entry and exit time into the magnetic field will minimize these symptoms.
There is no intended direct clinical benefit for the subjects participating in this study.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy Subjects
1. Healthy female subjects aged 18 or older
2. Has provided written informed consent prior to any study related procedures., OAB Subjects
1. Female subjects aged 18 or older
2. Has provided written informed consent prior to any study related procedures.
3. History of signs and symptoms of OAB including urinary frequency, urgency or urge incontinence for greater than or equal to 3 months.
4. At enrolment visit (V2) the subjects must have:
- At least 1 episode of urgency with or without incontinence in the last 3-day micturition diary.
- Frequency of micturition greater than or equal to 8 per 24 hours period during the 3-day micturition diary period
5. At the screening visit, the subject should be either naïve to OAB treatment (e.g no prior history of medications to treat lower urinary tract symptoms (LUTS), including OAB) or currently on treatment for LUTS (including OAB) and is willing to undergo a washout period for 3 weeks.

Exclusion criteria

Exclusion Criteria, 1. History of lower urinary tract symptoms (LUTS), including OAB (healthy subjects)
2. History of stress urinary incontinence, urethral sphincter incompetence and neurogenic detrusor overactivity .
3. History of signs or symptoms suggestive of urinary tract infection (confirmed by positive urine analysis).
4. History of bladder outlet obstruction (not including detrusor-overactivity)

for example bladder/vesicouterine pro-lapse (> grade II) or chronic obstruction.
5. History of urinary tract surgery less than or equal to 6 months prior to screening.
6. Has an indwelling catheter or permanent catheter fitted.
7. History of pelvic area radiotherapy treatment.
8. Uncontrolled diabetes mellitus.
9. History of fibromyalgia.
10. Pregnant or intends to become pregnant during the study or sexually active, of childbearing potential and is unwilling to utilize a reliable method of birth control (note: reliable methods are contraceptive pills of combination type, hormonal implants, injectable contraceptives, sexual abstinence and vasectomized partner).
11. Pregnancy within 6 months before screening or breast feeding within 3 months before screening.
12. History of positive hepatitis A, B surface antigen, hepatitis C antibody or HIV test result.
13. Any use of drugs of abuse within 3 months prior to screening visit.
14. History of smoking more than 10 cigarettes (or equivalent amount of tobacco) per day within 3 months prior to screening visit.
15. History of drinking more than 14 units of alcohol per week (1 unit = 10 g pure alcohol = 250 ml of beer (5%) or 35 ml of spirits (35%) or 100 ml of wine (12%) within 3 months prior to screening visit.
16. Has any changes to prescribed medication or to dose of prescribed medication less than or equal to 1 month prior to screening which in the opinion of the Investigator, will interfere with the study procedures or compromise safety.
17. Is currently receiving or has a history of treatment with alpha blockers, beta receptor blockers or agonists, botulinum toxin (less than 12 months), resiniferatoxin or pelvic floor muscle relaxants less than or equal to 9 months prior to screening.
18. Any clinically significant abnormality following the investigator*s review of screening physical examination.
19. Any clinically significant history of any other disease or disorder-gastrointestinal, cardiovascular, respiratory, renal, hepatic, neurological, dermatological, psychiatric or metabolic as judged by the medical investigator.
20. Abnormal pulse and/or blood pressure measurements at the screening visit as follows: Pulse <40 or >90 bpm; systolic blood pressure >140 mmHg; diastolic blood pressure >90 mmHg; blood pressure and pulse measurements after subject has rested for 10 minutes.
21. Participation in any clinical study within 3 months or participation in more than 3 clinical studies within 12 months, prior to the expected date of enrolment into the study, provided that the clinical study did not entail a biological compound with a long terminal half life.
22. Any clinical condition, which, in the opinion of the investigator would not allow safe completion of the study.
23. Employees of the MUMC University of Maastricht involved in the study.
24. Claustrofobia, preventing a patient to have an fMRI scan

25. patients with any metal imlants in the body (except dental implants) that would prevent the patients to undergo fMRI scan.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-05-2018
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL52605.068.15

Study results

Date completed: 18-07-2024

Summary results
Trial ended prematurely