An exploratory study to evaluate bladder contractions in the storage phase (non voiding activities) and related bladder sensation in healthy females and untreated females with Overactive Bladder (OAB) using high resolution and conventional urodynamics.

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To identify objective parameters to characterize Non Voiding Activity (NVA) in healthy and OAB subjects using high resolution urodynamic assessmentNVA are changes of pressure in the bladder lumen. These changes are measured as detrusor pressure (...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON37950

Source
ToetsingOnline

Brief title
Exploratory urodynamic study to bladdercontractions in storage phase

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Frequency and Urgency, Overactive Bladder

Research involving
Human

Sponsors and support

Primary sponsor: Astellas Pharma
Source(s) of monetary or material Support: Astellas Pharma Europe Ltd. (APEL)

Intervention

Keyword: bladder, contraction, overactive, urodynamics

Outcome measures

Primary outcome

Measuring and identifying nonvoiding activity with conventional and highresolution urodynamics in female patients suffering OABsc and healthy female volunteers.

Secondary outcome

- To identify NVA in healthy and OAB subjects using conventional urodynamic assessment

- To assess the subjects bladder sensations measured by visual analogue scale (VAS) and 5-points grading scale (Appendix 7 & 8) during the high resolution urodynamic and conventional assessments

- To assess the correlation between NVA and subjects bladder sensations

- To explore NVA in a subgroup of subjects defined by the severity of OAB symptoms collected as background information (3-days bladder diary)

- To illustrate the amount of NVA detected with high resolution urodynamic test methodology compared to NVA detected with conventional urodynamic assessments

- To assess symptoms severity, bother and its impact on quality of life using: OAB-Q short form and Uroginal Distress Inventory (UDI-6) questionnaires and a 3

Day micturition bladder diary as background information to characterize the

study population

Study description

Background summary

The International Continence Society (ICS) has defined Overactive Bladder syndrome (OAB) as a medical condition with symptoms of urgency, with or without incontinence, usually with frequency and nocturia, with no proven infection of obvious pathology.
Conventional urodynamic remains the gold standard for investigating lower urinary tract dysfunction.
High gain high resolution ambulatory urodynamics was developed using pilot data collected by Gillespie in collaboration with Kulseng Hanssen (unpublished data). Pilot experiments to test the technical capabilities have been performed using the Programming Ambulant System Acquition (Pasaq), a ISO 601 certified and developed by Instrument Development Engineering Evaluation (IDEE) department of the Maastricht University and approved by the hospital technical department. The PASAQ system will be used in combination with the unisensor microtip catheters that have been proven to be functional in regular ambulatory urodynamic measurements.
This will provide a higher sensitivity of the resolution than conventional urodynamic in term of frequency and amplitude of signals detected will enable the capture of bladder micro contractions activity or named throughout the protocol non voiding activity (NVA).

Study objective

To identify objective parameters to characterize Non Voiding Activity (NVA) in healthy and OAB subjects using high resolution urodynamic assessment
NVA are changes of pressure in the bladder lumen. These changes are measured as detrusor pressure (Pdet) calculated from substraction of intra-abdominal pressure (Pabd) from intra-vesical pressure (Pves). All Pdet with an amplitude of at least 1cm of water, frequency below 0.2 Hz and pulse duration between 5 and 60 seconds qualify as NVA.

Study design

This is a single site, exploratory study

Intervention

not applicable

Study burden and risks

Patients and healthy volunteers have to visit the function room of the urology department twice and they will be contacted by telephone at least once after these visits. At home (between visit 1 en 2) participants have to fill out questionnaires. At visit 2 participants will ondergo urodynamic inverstigation both conventional en highresolution urodynamics.
just like all people who undergo a urodynamic investigation the participants will be explored to a risk of devaloping a urinary tract infection and short-term hematuria. For both risk factors they will be able to consult the urology department.

Contacts

Public
Astellas Pharma

Lovett House
Middlesex, TW18 3AZ
GB
Scientific
Astellas Pharma

Lovett House
Middlesex, TW18 3AZ
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
Female subjects aged between 35 and 65 years
has signs and symptoms of OAB including urinary frequency, urgency or urge incontinence for greater than or equal to 3 months defined as:
- 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
Written informed consent
Healthy volunteers:
Healthy female subjects aged between 35 and 65 years .
Written informed consent

Exclusion criteria

Exclusion criteria patients and healthy volunteers:
1. History of stress urinary incontinence, urethral sphincter incompetence, neurogenic detrusor overactivity and overactive bladder.
2. History, signs or symptoms suggestive of urinary tract infection (confirmed by positive urine analysis), bladder outlet obstruction (not including detrusor-overactivity) for example bladder/vesicouterine pro-lapse (> grade II) or chronic obstruction.
3. History of urinary tract surgery less than or equal to 6 months prior to screening.
4. Has an indwelling catheter or permanent catheter fitted.
5. History of pelvic area radiotherapy treatment.
6. Uncontrolled diabetes mellitus.
7. History of fibromyalgia.
8. 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 or vasectomized partner).
9. Pregnancy within 6 months before screening or breast feeding within 3 months before screening
10. Has a positive pre-study hepatitis A, B surface antigen, hepatitis C antibody or HIV result at time of screening.
11. Any use of drugs of abuse within 3 months prior to screening visit.
12. History of smoking more than 10 cigarettes (or equivalent amount of tobacco) per day within 3 months prior to screening visit.
13. 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.
14. 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.
15. Any clinically significant abnormality following the investigator*s review of the pre-study physical examination and 12 lead ECG

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-03-2012
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	08-02-2012
Application type:	First submission
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
Other	ClinicalTrials.gov
CCMO	NL36150.068.11