The immunohistochemical characteristics of the obstructed human bladder

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

Summary

ID

NL-OMON47879

Source
ToetsingOnline

Brief title
Characteristics of the obstructed human bladder

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
benign prostate enlargement, urinary retention

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, immunohistochemistry, obstruction, urodynamics

Outcome measures

Primary outcome

Primary objective:

To investigate whether the immunohistochemical characteristics of the bladder wall are different in obstructed bladders showing detrusor overactivity (DO) compared to obstructed bladders without detrusor overactivity and bladder outlet obstruction (BOO) induced urinary retention

Secondary outcome

Secondary objective:

-To describe the immunohistochemical characteristics of the bladder wall and urethra

-To investigate possible microanatomical connections between nerves, ganglia and interstitial cells in the human bladder

-To investigate the distribution of receptors involved in bladder-urethral interactions in relation to bladder outlet obstruction

-Mapping of different structures and layers of the bladder during bladder outlet obstruction by using two-photon laser scanning microscopy (TPLSM)

Study description

Background summary

The overactive bladder syndrome (OAB) is a symptom complex of urgency accompanied by frequency with or without urgency urinary incontinence. It is a

highly prevalent disorder with a profound impact on quality of life and has many potential causes and contributing factors. One of these factors is an outlet obstruction of the bladder due to benign prostatic hyperplasia (BPH). Despite the projected demand for treatment, many patients with symptoms of an overactive bladder are inadequately treated. Moreover, if outlet obstruction and detrusor overactivity coincide, the treatment algorithm is still obscure. Nowadays antimuscarinic drugs are used for treatment of OAB symptoms. During the last decade studies concerning detrusor overactivity have been performed in animals to investigate the causes. As the rat and the guinea pig are the most frequently used species in this research field, it is important to point out that they show both from a structural and functional point of view, major differences compared to the human bladder. Rats specifically differ from humans in micturation behavior, as the guinea pig bladder differs in the effect of certain drugs like prostaglandines on the bladder. Therefore, it is of upmost importance to start with this immunohistochemical study in human bladder tissue and to compare this to bladder function. In particular, we aim to compare these characteristics in different phases of obstruction (OAB vs. complete urinary retention).

Study objective

The primary objective of this study is to describe the immunohistochemical characteristics of the bladder wall and urethra and to investigate possible microanatomical connections between nerves, ganglia and interstitial cells in the human bladder. Secondary, we want to investigate whether the immunohistochemical characteristics of the bladder wall are different in obstructed normo-active compared to obstructed overactive bladders and bladders after complete urinary retention. Furthermore, we aim to image these microanatomical characteristics of the bladder by using two-photon microscopy.

Study design

In this multicenter study the immunohistochemical characteristics of human bladder and urethra will be described. Bladder and urethra tissue from patients undergoing open suprapubic prostatectomy according to Hryntschak because of benign prostate hyperplasia will be used. During the operation in which the bladder is opened anyhow through an anterior incision, a full thickness bladder sample from the anterior wall with a diameter of 5mm and a length of 15mm will be taken. This will occur from one of the sides of the bladder incision needed to perform the operation. Only histologically normal regions of the bladder, not showing any signs of cancer or prominent inflammation, will be examined in this study.

Study burden and risks

Patients that participate in this study are not expected to be exposed to

serious adverse events and no site visits are presumed. They will be asked to fill in an ICS male LUTS questionnaire taking approximately 5 minutes. Patients will not have benefits of this study.

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

-Males above 18 years old with benign prostate hyperplasia
-Prostate volume of at least 60cc for which they undergo open prostatectomy according to Hryntschak

Exclusion criteria

-Neurological voiding disorders; including diabetes mellitus (severe or uncontrolled, or diabetes with peripheral nerve involvement), spinal cord injury, multiple sclerosis.
-Malignancy of the lower urinary tract, including prostate.
-Proven interstitial cystitis or clinical symptoms of interstitial cystitis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-02-2016
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO Date:	15-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-11-2019
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	NL45847.068.13