Non-invasive ultrasonic diagnosis of urinary Bladder Outlet Obstruction (BOO)

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To study in a small group of male volunteers the feasibility of estimating urinary flow velocity and turbulence caused by obstruction using rf ultrasound. Subsequently, to compare in a group of patients eligible for TURP according to clinical...

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

Summary

ID

NL-OMON40568

Source
ToetsingOnline

Brief title
Ultrasonic BOO diagnosis

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
bladder obstruction, Urethral obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: STW

Intervention

Keyword: Bladder outlet obstruction, Non-invasive measurement, Radiofrequency ultrasound, Urinary flow velocity and turbulence

Outcome measures

Primary outcome

The raw ultrasound data will be processed using Matlab procedures developed in an earlier study resulting in decorrelation curves.

Secondary outcome

In healthy volunteers from free flow-rate measurement:

Maximum urinary flow-rate and voided volume are quantitative parameters that will be derived using earlier developed Matlab procedures in the flowmeter setup. They will be used to verify/support the stratification of patients according to the degree of obstruction.

In patients from free flow-rate measurement:

Maximum urinary flow-rate and voided volume are quantitative parameters that are automatically calculated by Audact software used in the clinical urodynamic setups. The parameters are stored in Ms-Access databases in Erasmus MC servers. They will be to verify/support the stratification of patients according to the degree of obstruction.

In patients from invasive pressure flow study:

Detrusor pressure at maximum flow-rate

Maximum flow-rate

Urethral resistance parameters

URA (Urethral Resistance Factor)

BOOI (Bladder Outlet Obstruction Index)

Slope of lowest part of PURR (Passive Urethral Resistance Relation)

Bladder contractility parameters

Wmax (maximum bladder contractility)

BCI (Bladder Contractility Index)

These parameters will be used to relate the (de)correlation of the ultrasound images to the degree of obstruction and/or bladder contractility of the patients.

Study description

Background summary

From a clinical point of view, a simple and non-invasive measurement device that objectively grades and localizes urethral obstruction in one voiding would be a major breakthrough. Such a device would significantly lower the threshold for urodynamic testing in the increasing aging male patient population.

Study objective

To study in a small group of male volunteers the feasibility of estimating urinary flow velocity and turbulence caused by obstruction using rf ultrasound. Subsequently, to compare in a group of patients eligible for TURP according to clinical criteria an invasive routinely clinically derived measure of bladder outlet obstruction (BOOI, URA, slope of PURR) with criteria derived from the noninvasive rf ultrasound analysis. Finally to compare the results calculated from raw ultrasound data between the healthy volunteers and the obstructed patients.

Study design

This is a prospective, observational, exploratorive, pilot study.

Study burden and risks

There are no benefits and risks expected. The burden is minimal and consists of one or two non-invasive urodynamic measurements during one visit to Erasmus MC for the patient group. The healthy male volunteers group will exist of students and staff members of Erasmus MC. They will be asked to void a maximal number of 10 times, which means they have to come by maximal 10 times. Visits for this population will be planned on days on which the volunteers will already be present at Erasmus MC, so they don*t have tpo come to Erasmus MC especially for a study visit. Also both groups will be asked to fill out a questionnaire regarding lower urinary tract symptoms (the IPSS questionnaire) once. In case of incidental medical findings, the participant will be advised to visit a physician.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

1) Male 18 years or older
2) Healthy volunteers: student or staff member at Erasmus MC
3) Patients: eligible for TURP based on clinical criteria who will be urodynamically investigated at Erasmus MC
4) Mentally and physically able to visit the Erasmus MC
5) Signed informed consent

Exclusion criteria

1) Unable to urinate in a standing position
2) Previous lower urinary tract surgery
3) Congenital disease of the lower urinary tract

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2014
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL47107.078.13