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Contractility: cuff versus urodynamics testing in males with voiding lower urinary tract symptoms

Submission date
02/07/2018

Recruitment status
No longer recruiting

Registration date
06/07/2018

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A number of men will experience bothersome urinary symptoms, which become more common as they age. A number of conditions can cause these symptoms, and general practitioners may refer men to their local hospital for further assessment and treatment. Symptoms can include poor flow of urine, the need to pass urine more frequently, or the sensation that the bladder is not completely emptying. This can be due to an enlargement of the prostate gland. However, these symptoms may also be caused when the bladder muscle is unable to contract (squeeze) as well as it previously has to empty the bladder. This is known as an underactive bladder. It is important to distinguish between the two conditions as a cause for these symptoms, to prevent side effects from unnecessary medications or operations. Currently, men undergo a bladder pressure test (urodynamics). This involves a catheter inserted into the bladder, through which it is filled with fluid and the pressure measured. A second small tube is inserted into the rectum to measure the pressure in the abdomen. A second technique for measuring bladder pressures is the use of a small inflatable cuff which is placed around the penis (penile cuff test). The bladder pressure can then be assessed by inflating the cuff and interrupting the flow of urine. The bladder can be filled naturally before the test, which means a catheter tube will not be required. This study is designed to find out ways to make the penile cuff test more accurate, and compare this to results obtained from a bladder pressure test performed at the same time.

Who can participate?
Men aged over 18 years undergoing video-urodynamics (bladder pressure test)

What does the study involve?
Participants complete a bladder diary for 3 days at home and bring it to their appointment. They complete a symptom score and then undergo a urine flow test and an ultrasound assessment of post-void residual urine. Bladder and rectal catheters are then inserted for the standard bladder pressure test with x-ray screening. The patient's bladder is then refilled, a penile cuff is applied and a second void is performed (no x-ray screening) with the penile cuff test active. The patient's bladder is filled a third time and the line is removed from the bladder. A further void with the penile cuff test active is performed with x-ray screening of the bladder and urethra.

What are the possible benefits and risks of participating?
There are no direct benefits to participants. The results of this study will hopefully help improve the investigation of men with similar problems in the future. There are no serious risks involved in participating in this study. The risks of standard bladder pressure tests involve a small chance of blood in the urine temporarily following the test, or developing a urine infection. 2% of men find the penile cuff test uncomfortable, or may see blood in the urine following the test. The majority of men tolerate the test well. The standard bladder pressure test involves the use of x-rays to take images of the bladder and urethra. For this study x-rays are also taken during the second penile cuff test to examine the effect the cuff has on the urethra as it inflates. These procedures use ionising radiation to form images of your body and provide other clinical information. Ionising radiation can cause cell damage that may, after many years or decades turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect the participants. The standard bladder pressure test would increase this risk by a very small amount (0.003%). Taking part in this study will only increase the risk slightly – the same as if the standard test was done twice.

Where is the study run from?
Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2017 to January 2020

Who is funding the study?
Mediplus Limited

Who is the main contact?
Helen Morton
Helen.Morton@nuth.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Miss Helen Morton

Contact details
Department of Urology
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 (0)191 2139602
Helen.Morton@nuth.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT03603015

Protocol serial number
38747

Study information

Scientific Title
Contractility: cuff versus urodynamics testing in males with voiding lower urinary tract symptoms

Acronym
CONCUR

Study objectives
A number of men will experience bothersome urinary symptoms, which become more common as they age. A number of conditions can cause these symptoms, and general practitioners may refer men to their local hospital for further assessment and treatment. Symptoms can include poor flow of urine, the need to pass urine more frequently, or the sensation that the bladder is not completely emptying. This can be due to an enlargement of the prostate gland. These symptoms can also be caused when the bladder muscle is not able to contract (squeeze) as well as it previously has to empty the bladder. This is known as underactive bladder (UAB).
It is important to distinguish between the two conditions as a cause for these symptoms, to prevent side effects from unnecessary medications or operations. Currently, men would need to undergo a bladder pressure test (urodynamics). This involves inserting a catheter via the penis into the bladder, through which the bladder is filled with fluid and pressure is measured. A separate second small tube is inserted into the rectum to measure the pressure in the abdomen. The pressure changes are observed as the bladder is filled, and then urine is passed around the catheter.
A second technique for measuring bladder pressure is the use of a small inflatable cuff which is placed around the penis (penile cuff test). The bladder pressure can then be determined by inflating the cuff and interrupting the flow of urine. The bladder can be filled naturally before the test, which means a bladder catheter tube is not required. This study is designed to find out ways we can make the penile cuff test even more accurate, and compare this to results obtained from the bladder pressure test, and will take x-ray pictures of the urinary tract during the test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tyne & Wear South Research Ethics Committee, 25/06/2018, ref: 18/NE/0213

Study design
Non-randomized; Both; Design type: Diagnosis, Imaging, Other, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Specialty: Renal Disorders, Primary sub-specialty: Urology; UKCRC code/ Disease: Renal and Urogenital/ Other disorders of the genitourinary system

Interventions
Men over the age of 18 years old referred for video-urodynamics (bladder pressure test) are the target population of the study. Any patient meeting the eligibility criteria will be contacted over the telephone by the direct care team, and the study will be introduced. An IPSS patient symptom score will be performed to confirm eligibility. If the patient indicates that they would consider taking part in the study they will be scheduled for a urodynamics appointment in the urodynamics research session and an information leaflet sent out. As is standard care, the patient is also sent a frequency volume chart to complete for 3 days at home, and bring to their urodynamics appointment. When the patient attends for their appointment they will be met by a member of the research team. They will have the opportunity to ask questions, and the researcher will go through the process of informed consent. If the patient does not consent to participate their standard test only will be performed.

Patients who provide valid informed consent will complete a second symptom score (IPSS-MLUTS), and then undergo study investigation as follows:
1. Urine flow test and assessment of post void residual of urine. This is assessed by ultrasound examination by two members of the research team.
2. Insertion of bladder and rectal catheters for the standard bladder pressure test. The bladder catheter will be aspirated to ensure the bladder is empty at the start of the procedure.
3. Standard video-urodynamics will be performed (fill-void cycle) with x-ray screening.
4. The patient's bladder will be refilled, a penile cuff applied and a second void performed (no xray screening) with the penile cuff test active.
5. The patient's bladder will be filled a third time and the line from the bladder removed. A further void with the penile cuff test active will be performed with x-ray screening of the bladder and urethra.

Penile cuff tests will be evaluated by accepted quality control criteria to determine successful test. This sample size for this study is 30 patients with successful penile cuff tests.

Intervention Type
Other

Primary outcome(s)
1. Variance measured by calculating the mean difference and SD between cuff interruption pressure (pcuff.int) and intravesical pressure (pves.isv) at the single timepoint of this study. Reduction in variance will be measured by comparing this result to previous data using an F test
2. Urethral behaviour and bladder neck opening during x-ray screening of penile cuff test, reported by qualitative description

Key secondary outcome(s))
1. Comparison of non-invasive vs invasive indices of contractility will measure correlation between pcuff.int from the cuff test against BCI and Watt’s factor from CMG performed at the single timepoint of this study

2. Correlation of PROMs using IPSS and ICIQ-MLUTS measured at baseline
3. Accuracy of ultrasound post-void residual measurement measured by catheterised residual volume (mL) during 1st catheterisation at the single timepoint of this study

Completion date
05/01/2020

Eligibility

Key inclusion criteria
1. Male participant aged 18 years old or over
2. Referred for investigation of urinary symptoms by video-urodynamics in our unit
3. Predominant voiding urinary symptoms (assessed by international prostate symptom score - IPSS - at screening. Included if score from voiding symptoms is a greater percentage of total score than storage symptoms)
4. At least two voids on their frequency volume chart of greater than or equal to 250 mL
5. Patient has capacity to understand the study procedures and give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. All female patients
2. Any male patient less than 18 years of age
3. Inability to void
4. Long-term catheterisation
5. Predominant storage urinary symptoms on IPSS score
6. Fewer than 2 voids on frequency volume chart greater than or equal to 250 mL
7. Known pre-existing neurological cause for symptoms
8. Active UTI

Date of first enrolment
29/08/2018

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Mediplus Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Helen Morton (helen.morton@nuth.nhs.uk). This would be for medical professionals with an interest in non-invasive urodynamics requiring data for meta-analysis, or in response to queries/requests generated from publication of results in scientific journals/presented at conferences. This will be from the overall end point of the study (05/01/2020) and will be anonymised raw data only. This will be shared in a password protected file sent via an encrypted email service. Consent has been taken from patients following provision of a patient information sheet and data transparency information sheet.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version v1.0	14/05/2018	06/07/2018	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.1	15/05/2018	06/07/2018	No	No