

Accuracy of Bladder Ultrasound Study (BUS)

Submission date 07/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/09/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/09/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Overactive bladder syndrome is often described as urgency that occurs with or without incontinence and usually with an increased frequency of urination and the need to go to toilet in the night. In a UK study, overactive bladder symptoms were found in 12% of the general population. In individuals over 40 years of age, 34% report significant lower urinary tract symptoms. Urinary symptoms alone can be unreliable in diagnosing overactive bladder syndrome, so some doctors recommend a test called urodynamics. With this test, we can diagnose whether the bladder muscle is overactive (detrusor overactivity). Urodynamics involves a catheter inserted in the urethra (the tube from the bladder to outside of the body) which can cause discomfort and carries a small risk of infection. An alternative is to measure the thickness of the bladder wall by ultrasound. This is a simpler, more, comfortable test. We do not know for certain how accurate ultrasound will be at detecting detrusor overactivity that is why we are undertaking this research study.

Who can participate?

All women who have been referred to this hospital by the GP with symptoms of increasingly frequent toilet visits or feel a sudden urgent need to pass urine are being invited to take part. It is hoped 600 women from several hospitals will take part in the study.

What does the study involve?

If you agree to take part, we will measure the bladder wall thickness by means of an ultrasound examination, which obtains images of the body without the use of x-rays. In order to perform this scan it is necessary to gently insert the tip of an ultrasound probe into the vagina. This is a simple and usually painless procedure. The probe is a little bigger than the size of a finger or a tampon, and produces pictures on a TV screen. . The test will take no more than five minutes to perform. You will then have the test called urodynamics. This is the test which the doctors may perform regardless of whether you are in the study to confirm the diagnosis. We (the researchers) would also like women to answer some questions of acceptability, quality of life and disease severity. You will be given an anonymous questionnaire to complete before you leave hospital as we want to find out the how you found the tests and the research study. We will also ask you to fill in some of these questionnaires, six months after your tests, to give us an idea of any treatment you may have received.

What are the possible benefits and risks of participating?

We hope that the test results will help you get the most appropriate treatment for your urinary symptoms without further tests. However, there may be no benefit from taking part. Also, of course, the information we get from this study may in the future help us reduce the need for urodynamics in women with overactive bladder. All women who participate in the study will undergo a urodynamics to confirm the diagnosis. This involves some discomfort and 5% risk of urinary tract infection

Where is the study run from?

The central study organisers are based at the University of Birmingham. The Clinical Trials Unit at the University of Birmingham will collect and analyse the data.

When is the study starting and how long is it expected to run for?

The study began recruiting in April 2011 and is due to continue recruiting until April 2013, with follow up and reporting being completed by December 2013.

Who is funding the study?

The study is funded by a grant from the NIHR Health Technology Assessment programme.

Who is the main contact?

The BUS study office
bus-study@contact.bham.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

HTA 09/22/122, Version 5.0

Study information

Scientific Title

Accuracy of Bladder Ultrasound in the diagnosis of Detrusor Overactivity (DO): a study to evaluate if ultrasound can reduce the need for urodynamics

Acronym

BUS

Study objectives

The study will evaluate the accuracy of BUS in making a diagnosis of DO using laboratory multichannel urodynamics (UDS) as the reference standard. For the index test (BUS), we will measure bladder wall thickness from transvaginal ultrasound scans, which will be a continuous variable reported in millimetres. For reference standard, UDS will be performed on all patients for DO verification. Other variables and results of routinely performed tests will also be obtained, and will be used for evaluation of the add-on value of BUS. Health economic evaluation will be performed to establish the relative cost-effectiveness of BUS alone and in combination with existing tests.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0922122>

Protocol can be found at: http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0012/54300/PRO-09-22-122.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Nottingham 2, 17/08/2010, ref: 10/H0408/57

Study design

Diagnostic (test accuracy) study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Overactive bladder syndrome

Interventions

The bladder wall thickness will be obtained by means of an ultrasound examination. In order to perform this scan it is necessary to gently insert the tip of an ultrasound probe into the vagina. This is a simple and usually painless procedure.

For reference standard, UDS will be performed on all patients for DO verification.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The BUS testing procedure will be standardised in the first phase of the study and criteria for interpretation have been determined a priority. The first objective of the study is to determine the accuracy of BUS in the diagnosis of DO. To do this, the comparison of BUS against UDS will be made and estimates of sensitivity, specificity, predictive values, likelihood ratios and their 95% confidence intervals calculated.

Key secondary outcome(s)

To investigate the value added by BUS to information already obtained from routinely used initial non-invasive tests (history, bladder diary, urine dipstick).

Completion date

31/12/2013

Eligibility

Key inclusion criteria

1. Frequency of 9 or more voids in 24 hours as reported in the 3 day bladder diary at least on one of the days
2. Mild - severe urgency (cannot defer the urge to void) on at least one occasion in 3 day bladder diary
3. Post void residual volume <100 mls on screening
4. Written informed consent
5. If patient has had previous stress incontinence surgery &/or Botox, it was >6 months ago

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Pregnancy and up to 6 weeks postpartum
2. Pure symptoms of stress incontinence or stress predominant mixed incontinence
3. Evidence of cystitis (dipstick positive for leucocytes/nitrites)
4. Voiding difficulties (post void residual >100 ml)
5. Prolapse > grade II (any compartment)
6. Urodynamics, assessment in the past 6 months
7. Use of antimuscarinics for more than 6 months continuously.
8. Current use of anti-muscarinics (e.g. Tolterodine, solifenacin, oxybutynin). If the woman is taking anti-muscarinics at the point of consent, she will be eligible if medication is ceased immediately
9. There is a delay of at least 2 weeks until the index and reference tests are carried out.

Date of first enrolment

01/04/2011

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Birmingham Women's Hospital

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

Organisation

Birmingham Women's NHS Foundation Trust (UK)

Organisation

University of Birmingham

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes