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Accuracy of Bladder Ultrasound Study (BUS)

Submission date
07/06/2012

Recruitment status
No longer recruiting

Registration date
18/09/2012

Overall study status
Completed

Last Edited
20/09/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
http://www.bus.bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Pallavi Latthe

Contact details
Birmingham Women's Hospital
Metchley Drive
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 627 2672
Pallavi.Latthe@bwhct.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Diagnostic (test accuracy) study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please contact bus-study@contacts.bham.ac.uk to request a patient information sheet

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 measure
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.

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

Overall study start date
22/03/2011

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

Age group
Adult

Sex
Female

Target number of participants
600

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
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 7618
b.w.laverty@bham.ac.uk

Sponsor type
University/education

Website
http://www.rcs.bham.ac.uk

Organisation
Birmingham Women's NHS Foundation Trust (UK)

Sponsor details
Metchley Park Road
Edgbaston
Birmingham
England
United Kingdom
B15 2TG

Sponsor type
Hospital/treatment centre

Organisation
University of Birmingham

Sponsor details

Sponsor type
Not defined

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

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