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Female urgency, trial of Urodynamics as routine evaluation

Submission date
11/09/2017

Recruitment status
No longer recruiting

Registration date
14/09/2017

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Overactive bladder (OAB) affects 12-14% of the adult female population in the UK. Symptoms include increased frequency (going to pass urine more frequently), urgency (being unable to hold-on), urgency incontinence (UUI), and waking up at night to pass urine. Although rarely life-threatening, OAB can have a considerable negative impact on patients' quality of life, restricting their social life and ability to work, and up-to social isolation in severe cases. OAB is first treated with lifestyle changes (such as reducing caffeine intake), pelvic floor exercises, bladder training and certain medications. Unfortunately these treatments do not work in 25-40% of patients (i.e. refractory OAB). These patients may be offered second line treatments such as injections of BOTOX into the bladder wall or SNM (an implant in the buttock which aim to regulate the bladder nerves in the lower spine). Before recommending second line treatments, doctors are advised to perform a diagnostic invasive test called "Urodynamics" to confirm the diagnosis. The test involves passing a thin tube into the bladder and another one into the back passage to measure the bladder activity and episodes of urinary incontinence (UI). Patients often find Urodynamics embarrassing and uncomfortable and some get cystitis (bladder infection) after the test. When asked, patients felt the test could be justified if it improves the treatment outcomes. However, in almost 40% of patients, Urodynamics does not show the underlying cause of the bladder problem and therefore is unable to guide doctors and patients in their decision making. The aim of this study is to assess whether routinely performing Urodynamics, in addition to the standard comprehensive clinical assessment, improves the outcome of treatments in women with refractory OAB compared to comprehensive clinical assessment only.

Who can participate?
Women aged 18 and older who have an overactive bladder (OAB).

What does the study involve?
Participants are randomly allocated. Those in the first group receive the standard clinical assessments as per their local NHS practice. Participants in the second group receive the Urodynamics test in addition to the comprehensive clinical assessment. Participants are posted questionnaires at three, six and 15 months after being allocated to groups to ask about their bladder symptoms, their quality of life and their views and experience with the treatment pathways.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There are no anticipated disadvantages or risks to participants in taking part in this study. Whichever group they are allocated to, the tests and assessments are performed by competent and trained clinicians. However it is important to note that there are risks associated with every test or treatment, and as part of routine clinical care, participants will be well informed of these potential risks. Steps are always taken to ensure that these risks are minimised.

Where is the study run from?
This study is being run by the University of Aberdeen (UK) and takes place in hospitals and treatment centres in the UK.

When is the study starting and how long is it expected to run for?
May 2017 to January 2025

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
Dr Suzanne Breeman

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
223787

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 36043

Study information

Scientific Title
Female Urgency, Trial of Urodynamics as Routine Evaluation (FUTURE study); a superiority randomised clinical trial to evaluate the effectiveness and cost effectiveness of invasive urodynamic investigations in management of women with refractory overactive bladder symptoms

Acronym
FUTURE

Study objectives
Hypotheses:
1. Whether routine Urodynamics investigation and comprehensive clinical assessment significantly improves patient-reported success rates following treatment, compared to comprehensive clinical assessment only
2. Assess the cost-effectiveness of routine Urodynamics investigation and comprehensive clinical assessment, compared to comprehensive clinical assessment only

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/03/2017, North of Scotland Research Ethics Service (Summerfield House, Aberdeen, AB15 6RE, United Kingdom; +44 1224 558458; gram.nosres@nhs.scot), ref: 17/NS/0018

Study design
Randomized; Both; Design type: Treatment, Diagnosis, Active Monitoring, Validation of investigation/therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reproductive Health and Childbirth

Interventions
Participants are randomly allocated to one of two arms for their urodynamics investigation. urodynamics investigation in addition to clinical assessment. Participants are randomised using a web-based application based at the Centre for Healthcare Randomised Trials (CHaRT).

Comprehensive clinical assessment arm:
Participants undergo a detailed history including:
1. Assessment of Urinary symptoms: storage, filling and incontinence symptoms and the most bothersome urinary symptoms
2. Previous investigations and/ or treatments (conservative, pharmacological and or surgical) for UI and OAB
3. Past medical or surgical history of relevance
Participants also undergo a clinical examination including assessment for:
1. Stress urinary incontinence
2. Pelvic organ prolapse
3. Pelvic masses and other pelvic pathology
And finally participants have non invasive clinical assessments completed including:
1. Evaluation of Bladder Diary for 3 days to assess daytime frequency; nocturia; urgency and UUI episodes
2. Post voiding residual urine volume using a bladderscan

Urodynamics and Comprehensive clinical assessment arm:
Participants in this group receive the some comprehensive clinical assessments as the other arm however they also have a urodynamic clinical assessment. Urodynamics refers to comprehensive invasive and non invasive assessment of women with urinary symptoms and includes:
1. Detailed history, examination and bladder diary as above
2. Subtracted cystometry
3. Free uroflowmetry ± pressure flow studies ± Bladderscan

Participants are followed-up at three, six and 15 months post-randomisation by postal questionnaire. The questionnaires ask about their bladder symptoms, their quality of life and their views and experience with the treatment pathways.

Intervention Type
Other

Primary outcome(s)
1. Participant reported success is measured using the Patient Global Impression of Improvement – Index (PGI-I) at 15 months post randomisation (approximately 12 months post treatment).
2. Economic outcome is the incremental cost per quality adjusted life year (QALY) gained of Urodynamics and comprehensive clinical assessment compared to comprehensive clinical assessment only, modelled over the lifetime of the patients

Key secondary outcome(s))
1. Proportion of women receiving invasive treatment is measured by review of the clinical health records at 6 and 15 months post randomisation
2. Participant reported outcomes at 3, 6 and 15 months post randomisation which includes:
2.1. OAB symptoms measured by the ICIQ-OAB and UPS
2.2. Urgency and UUI episodes measured using the bladder diary
2.3. Other urinary symptoms measured using the 3 domains of the ICIQ-FLUTS (filling, voiding and incontinence) and the bladder Diary
2.4. Generic health related QoL status measured using general (EQ-5D-5L) and condition specific (ICIQ-LUTSqol) QoL assessment tools
3. Adverse Events is measured by review of the clinical health records at 6 and 15 months post randomisation
4. Qualitative study outcomes which includes:

4.1. Participants' attitudes to invasive testing and expected outcomes (prior to randomisation or knowing their allocated study group) at baseline
4.2. Participants' attitudes to potential treatment options (prior to randomisation or knowing their allocated study group) at baseline
4.3. Participants' experience of Urodynamics and opinions regarding treatment outcome to include evaluation of treatment satisfaction or desire for further treatment (3 to 6 months post treatment)
4.4. Surgeon attitudes to the influence of Urodynamics on decision making at start of the study and 6 to 12 months after starting recruitment at their sites
5. Secondary economic outcomes which includes:
5.1. Incremental cost per QALY gained of Urodynamics and comprehensive clinical assessment compared to comprehensive clinical assessment only up to 15 months
5.2. Incremental cost per QALY gained of BoNT-A vs SNM as the initial treatment for refractory OAB over the lifetime of patients
5.3. Incremental cost per QALY gained of SNM test and BoNT-A treatment according to clinical assessment only compared to treatment guided by Urodynamics over the lifetime of patients
5.4. Expected value of perfect information and associated partial values over the lifetime of patients

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Women aged ≥18 years with refractory OAB or urgency predominant MUI in whom OAB are their most bothersome symptom
2. Have failed conservative treatment (as per NICE guideline e.g. pelvic floor muscle training/ bladder retraining)
3. Have failed or have not tolerated pharmacological treatment (at least 2 different drugs) unless contra indicated
4. Being considered for further treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
1103

Key exclusion criteria
1. Predominant SUI symptoms
2. Previous urodynamics in the last 12 month
3. Pelvic malignancy or clinically significant pelvic mass
4. Bladder Pain Syndrome
5. Neurological disease (e.g. Parkinson's disease, Spinal injuries, etc)
6. Urogenital fistulae
7. Previous treatment with BoNT-A/ SNM
8. Previous pelvic radiotherapy
9. Prolapse beyond introitus
10. Pregnant or planning pregnancy
11. Recurrent UTI where a significant pathology has not been excluded
12. Unable to give an informed consent

Date of first enrolment
01/10/2017

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Aberdeen Royal Infirmary
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Study participating centre
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Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Organisation
NHS Grampian

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available at the end of the study upon request from the Chief Investigator. Requests should include a scientific proposal including objectives. Proposals will be assessed by members of the trial steering committee and a decision made about the appropriateness of the request. The data will only be shared after a Data Sharing Agreement is fully executed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/03/2025	27/03/2025	Yes	No
Results article		01/07/2025	07/07/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes