

A multicentre pilot study to assess the feasibility of a future randomised controlled trial to investigate whether carrying out invasive bladder function tests in women about to undergo operations for stress incontinence alters the outcome of their surgery

Submission date 04/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/06/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 29/03/2018	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

Between 3-5 million women in England and Wales have stress urinary incontinence (SUI) or mixed urinary incontinence (MUI). SUI is leakage of urine resulting from weakness of the muscles of the pelvic floor, and it happens particularly when coughing, laughing or standing up. MUI is a combination of SUI and urge urinary incontinence, which is when women feel a sudden strong need to pass urine and some leaks before they can get to a toilet. In 85% of hospitals, invasive urodynamic testing (IUT) is used to try to find out how a woman's bladder is working and to decide what surgical or non-surgical treatments may be effective. In IUT a tube (catheter) is passed into the bladder. The tube is used to fill the bladder with fluid and a sensor measures changes in pressure within the bladder while it is fills and empties and also while the woman coughs, jumps, changes position and urinates. The tests can be uncomfortable and worrying for women, and sometimes can result in a bladder infection (cystitis). Many experts in the UK and around the world have tried to decide whether IUT is always worth doing, but still not enough research has been done to prove with certainty whether IUT really helps doctors and patients decide on the best treatment. So the question remains: does invasive urodynamic testing help doctors and patients to choose the best treatment, or would doctors be able to advise patients just as well without the tests? The best way to answer the question would be a study in which women who agreed to take part would be placed randomly (by chance, like tossing a coin) into one of two groups: in one group, women's treatment would be chosen following IUT, and in the other their treatment would be chosen without the tests. In this way researchers would be able to see whether the tests resulted in better treatment choices and therefore better results for the women: was their incontinence improved or cured, did they have more or fewer infections or other complications, was their quality of life during and after treatment better or worse; did they avoid any unnecessary or inappropriate surgery or other treatment? However, such a study

would be large and expensive, and so it is important that it is designed correctly. This study is a smaller study that will help to prepare for a future large study. It will 'rehearse' the main study with the aim of identifying any difficulties at an early stage. By also surveying the doctors who might enter their patients into a future study and talking to the women who take part (or choose not to), this study will make sure that the large study is practicable and acceptable to doctors and patients alike, and will be able to answer the questions that patients and doctors want to know the answers to, so that it will be effective and a good use of taxpayers' money.

Who can participate?

Women with stress urinary incontinence or stress-predominant mixed urinary incontinence

What does the study involve?

Participants are randomly allocated to undergo clinical assessment with non-invasive tests, or to undergo clinical assessment with non-invasive tests plus IUT.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Royal Victoria Infirmary (UK)

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

January 2011 to December 2012

Who is funding the study?

NETSCC Health Technology Assessment Programme

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?: a pragmatic multicentre pilot study to assess the feasibility of a future randomised controlled trial

Acronym

INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?)

Study objectives

1. A randomised controlled trial to investigate the clinical utility of invasive urodynamic investigation in women prior to surgical treatment of stress urinary incontinence is feasible.
2. Carrying out invasive urodynamic investigation prior to surgical treatment does not affect patient outcomes in women with stress or stress predominant mixed urinary incontinence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle & North Tyneside 1 Research Ethics Committee, ref: 10/H0906/76

Study design

A mixed methods study to assess feasibility of a future randomised controlled trial: (1) a pragmatic multicentre randomised pilot trial; (2) a survey of clinicians; (3) qualitative interviews with women and clinicians.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stress urinary incontinence in women

Interventions

Invasive urodynamic testing; dual-channel subtracted cystometry with simultaneous pressure /flow voiding studies is the most commonly applied technique in the evaluation of patients prior to surgery for stress urinary incontinence in most centres. The clinical utility of invasive tests will be judged against the comparator of basic clinical assessment supplemented by non-invasive tests including frequency/volume charting or bladder diary, mid-stream urine culture, cough stress test, urine flow rate and residual urine volume measurement. This study is NOT intended to examine the outcomes of specific surgical procedures.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The aim of this feasibility study is to estimate (via the pilot trial) rates of patient recruitment, randomisation, retention and response, logistics of trial methodology, and resource utilisation, and (via the clinician survey & interviews) clinicians' willingness to randomise. Qualitative patient interviews will explore understandings and experiences of the study, including participation decisions. In addition, estimation of the parameters of the primary outcome (from the pilot trial) would allow the sample size of a definitive trial to be determined.

The proposed primary outcome of the future definitive trial is the International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms (ICIQ-FLUTS - combined score) at 6 months after treatment.

Key secondary outcome(s)

Secondary outcomes of the definitive trial will include:

1. SF-36 general health questionnaire
2. Quantification of urinary leakage by
 - 2.1. Bladder diary
 - 2.2. International Consultation on Incontinence Questionnaire - Urinary Incontinence, Short Form (ICIQ-UI SF)
3. Prevalence of symptomatic 'de novo' functional abnormalities including voiding dysfunction and detrusor overactivity (subscales of ICIQ-FLUTS, with cystometry in symptomatic patients)
4. Impact of urinary symptoms on quality of life (ICIQ-LUTSqol)
5. Utility values computed from EQ-5D & SF-6D
6. Costs

These will all be rehearsed within the pilot study with a view to refining the choice of secondary outcomes for the main trial, based on data yield and quality. Longer term follow-up may also be considered as a secondary outcome in the definitive trial.

Completion date

31/12/2012

Eligibility**Key inclusion criteria**

Women with a clinical diagnosis of stress urinary incontinence or stress predominant mixed urinary incontinence, who have completed their family, and have undergone a course of pelvic floor muscle training (+/- other non-surgical treatments for their urge symptoms) with inadequate resolution of their symptoms, where both the woman and clinician agree that surgery would be an appropriate and acceptable next line of treatment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Symptomatic utero-vaginal prolapse requiring treatment
2. Previous surgery for urinary incontinence or pelvic organ prolapse
3. Neurological disease causing urinary incontinence
4. Unable to give competent informed consent

Date of first enrolment

04/01/2011

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Victoria Infirmary

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/05p40t847>

Funder(s)**Funder type**

Government

Funder Name

NETSCC Health Technology Assessment Programme. Project no. is 09/22/136

Results and Publications

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	01/02/2015		Yes	No
Results article	results	08/09/2015		Yes	No
Results article	substudy results	26/10/2016		Yes	No
Results article	cost-effectiveness results	23/03/2018		Yes	No
Protocol article	protocol	06/07/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes