ISRCTN71327395 https://doi.org/10.1186/ISRCTN71327395

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

Registration date
07/06/2010

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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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Study website
http://www.investigate-trial.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.investigate-trial.com/INVESTIGATE-trial/Patient_information.html

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 measure
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.

Secondary outcome measures
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.

Overall study start date
04/01/2011

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

Age group
Adult

Sex
Female

Target number of participants
60 responses per arm required; allowing for 50% losses at recruitment, randomisation and response stages up to 240 patients will be approached

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
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

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?
Protocol article	protocol	06/07/2011		Yes	No
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