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Adjustable anchored Single-Incision Mini-Slings versus standard tension-free mid-urethral slings in the surgical management of female stress urinary incontinence

Submission date
10/01/2014

Recruitment status
No longer recruiting

Registration date
14/01/2014

Overall study status
Ongoing

Last Edited
30/08/2023

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
Stress incontinence is the involuntary leakage of urine during physical activity, effort, exercise, or simply coughing or laughing. The aim of the study is to compare the current surgical treatment with a newer type of surgery. The current standard surgical treatment, Standard Mid-urethral Slings (SMUS), involves insertion of a special sling (mesh/ tape) underneath the urethra (bladder outlet) to provide support and help to prevent urinary leakage. The standard procedures have good success rates (85%) and high patient satisfaction rates. They require the patient to have a general anaesthetic. The newer procedure (SIMS: Single Incision Mini-Slings) has more recently been developed. This is a mini-version of the standard procedure and uses the same type of tape material. However, it requires a single cut in the vagina and is less invasive, and hence can be performed under local anaesthetic with less discomfort. It has been shown to have earlier recovery and earlier return to work and normal activities.

Who can participate?
Women who are scheduled for having surgery to treat stress urinary incontinence (SUI) can participate in this study. The potential participants are only approached to participate in the study if/when they have made their informed decision, according to the local standard clinical practice, to undergo SMUS procedure, Potential participants will be advised to refer to the trial patient information leaflets and discuss with their surgeons.

What does the study involve?
Women are randomly allocated to one of the two surgery types provided that their surgeon agrees that either type of surgery is suitable and after following the local standard clinical care procedures. All women are asked to complete assessment questionnaires at certain time points - before surgery and again at 4 weeks, 3 months and annual for 3 years after surgery. Women also complete a 14-day diary immediately after their operation. The study has been extended to include a 10 year follow-up.

What are the possible risks of participating?
There are no benefits associated with participating. Obviously there are risks associated with any surgical procedure but we do not think that there are disadvantages or additional risks to participants by participating in the study. Whichever group women are allocated to, their operation will be performed by a competent and trained surgeon. There are risks associated with all procedures and anaesthetics which will be explained to women, as per standard clinical care, prior to surgery. Steps are always taken to ensure that these risks are minimised.

Where is the study run from?
Aberdeen Royal Infirmary and 22 other NHS hospitals (UK)

When is the study starting and how long is it expected to run for?
December 2013 to November 2027 (updated 08/07/2021, previously: November 2020) (updated 01/02/2021, previously: February 2021) (updated 11/01/2021, previously: February 2020)

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

Who is the main contact?
Centre for Healthcare Randomised Trials
chart@abdn.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3/069/13

Study information

Scientific Title
Adjustable anchored Single-Incision Mini-Slings versus standard tension-free mid-urethral slings in the surgical management of female stress urinary incontinence: a pragmatic multicentre non-inferiority randomised controlled trial

Acronym
SIMS

Study objectives
The patient-reported success rate following surgical treatment with the adjustable anchored Single Incision Mini-Slings (SIMS) procedure is non-inferior to the tension-free Standard Mid-urethral Slings (SMUS) procedure while the former is associated with less post-operative pain, shorter hospital stay, earlier recovery and consequently earlier return to usual activities/work and is more cost-effective than SMUS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service Committee 2, 12/12/2013, ref: 13/NS/0143

Study design
Multicentre randomised controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Adult women with stress urinary incontinence

Interventions
Current intervention as of 17/05/2022:
The interventions being compared are:
1. Tension-free standard mid-urethral slings (SMUS) including RP-TVT and TO-TVT
2. Adjustable anchored single-incision mini-slings (SIMS)

SMUS will be performed under general anaesthetic (GA) or deep intravenous sedation while adjustable anchored SIMS will be done under local anaesthetic (LA) as an opt-out policy.

All participants, in both arms, will receive pre-and post-operative analgesia and antibiotics as appropriate. A cystoscopy (rigid or flexible) will be performed in all women following insertion of the sling, regardless of the study arm. No vaginal packs or catheters will be routinely inserted.

Postoperatively all participants will undergo voiding assessment including assessment for post-voiding residual urine volume (PVR) using a bedside bladder-scanner.

The study has been extended to include a long-term follow-up at 10 years. This will also include a qualitative component to explore:
1. Patient experiences of treatment and impact on QoL
2. Patient perceptions of decision process and decision outcomes (e.g., decisional regret and decisional conflict)
3. Patient satisfaction with treatment outcomes

All women who received their allocated treatment and have not withdrawn their consent within the initial follow-up period (3 years) are eligible to participate in the qualitative component of the long-term follow-up. Purposive (nonprobability) sampling will be used to ensure the diverse characteristics of the population sampled (e.g. arm of study, study outcome including those who have experienced mesh-related AEs such as erosion, pain and or further surgery to remove mesh). The study team anticipates interviewing a minimum of 23 to 27 participants in total.

Previous intervention:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 08/07/2021:
1. Patient-reported success rate measured by the validated Patient Global Impression of Improvement (PGI-I) at 12 months and 10 years
2. Incremental cost per QALY gained at 12 months and 10 years

Previous primary outcome measure:
1. Patient-reported success rate measured by the validated Patient Global Impression of Improvement (PGI-I) at 12 months
2. Incremental cost per QALY gained at 12 months

Secondary outcome measures

Current secondary outcome measures as of 08/07/2021:
1. Complications including: lower urinary tract injuries; haemorrhage (blood loss ≥ 200 ml); post-operative voiding dysfunction; pain, mesh extrusion/erosion, dyspareunia, long-term self-catheterisation, new-onset urgency/urgency incontinence assessed as appropriate at 3 and 12 months then yearly up to 3 years
2. Post-operative pain using a pain Numerical Rating Scale (NRS) assessed day 1-14
3. Objective success rates assessed by 24-hour pad test at 12 months and yearly up to 3 years
4. Other lower urinary tract symptoms using the International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms long form (ICIQ-FLUTS) and/or short form (ICIQ-SF) at 3 and 12 months and yearly up to 3 years
5. Health-related quality of life (QoL) profile (area under the curve) derived from EQ-5D, pain scores and ICIQ-LUTS quality of life measurements at 1, 3, and 12 months, yearly up to 3 years, and 10 years
6. Impact on sexual function derived from ICIQ-FLUTsex/ or PISQ-IR measurements at 12 months, yearly up to 3 years, and 10 years
7. Recurrence of SUI, re-operation rates for SUI, further treatment received such as physiotherapy, medical treatment (selective noradrenaline re-uptake inhibitors and/ or anti-muscarinic treatment)
8. Composite outcome of success using PGI-I and no requirements for further continence surgery at 10 years

Secondary economic outcomes include:
1. NHS and patient primary and secondary care resource use and costs at 3 months, 12 months and yearly up to 3 years
2. Incremental cost-effectiveness derived from responses to the ICIQ-LUTS over the follow-up period at 12 months and yearly up to 3 years
3. Incremental net benefit (NB) calculated from the responses to the discrete choice experiment (DCE) at 12 months

Previous secondary outcome measures:
1. Complications including: lower urinary tract injuries; haemorrhage (blood loss ≥ 200 ml); post-operative voiding dysfunction; pain, mesh extrusion/erosion, dyspareunia, long-term self-catheterisation, new-onset urgency/urgency incontinence assessed as appropriate at 3 and 12 months then yearly up to 3 years
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1. NHS and patient primary and secondary care resource use and costs at 3 months, 12 months and yearly up to 3 years
2. Incremental cost-effectiveness derived from responses to the ICIQ-LUTS over the follow-up period at 12 months and yearly up to 3 years
3. Incremental net benefit (NB) calculated from the responses to the discrete choice experiment (DCE) at 12 months

Overall study start date
01/12/2013

Completion date
03/11/2027

Eligibility

Key inclusion criteria
1. Women aged 18 years or over with stress urinary incontinence (SUI), who have been referred to one of the collaborating units from across the UK, and for whom surgery has been indicated
2. Women will have completed their families, failed or declined conservative treatment (supervised pelvic floor muscle training - PFMT)
3. All women will have urodynamic stress incontinence, or urodynamic mixed urinary incontinence with predominant SUI bothering symptoms
4. The small group of women with pure symptoms and signs of SUI and no symptoms of overactive bladder (OAB) or voiding dysfunction (VD) can be included without urodynamic investigations as per the updated NICE guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600

Total final enrolment
600

Key exclusion criteria
1. Anterior or apical prolapse ≥ pelvic organ prolapse quantification score (POP-Q) Stage 2
2. Previous incontinence surgery (for SUI or OAB)
3. Mixed incontinence with pre-dominant OAB symptoms (defined as OAB failed to be controlled

on conservative treatment such as bladder retraining, PFMT and/or anti-muscarinic treatment)
4. Neurological conditions e.g. MS, spinal cord injuries
5. Concomitant surgery at time of SUI surgery
6. Previous pelvic irradiation
7. Pregnancy or planning for a family
8. Inability to understand the information leaflet and consent form in English

Date of first enrolment
04/02/2014

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Aberdeen Royal Infirmary
Foresterhill
Aberdeeen
United Kingdom
AB25 2ZB

Study participating centre
Borders General Hospital
Melrose
United Kingdom
TD6 9BS

Study participating centre
Queen Margaret Hospital
Whitefield Road
Dunfermline
United Kingdom
KY12 0SU

Study participating centre
Princess Royal Hospital
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
York Teaching Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
New Cross Hospital
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Milton Keynes Hospital
H8 Standing Way
Eaglestone
Milton Keynes

United Kingdom
MK6 5LD

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Ayrshire Maternity Unit
University Hospital Crosshouse
Kilmarnock Road
Crosshouse
Ayr
United Kingdom
KA2 OBE

Study participating centre
Monklands Hospital
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Countess of Chester Hospital
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Upton

Birkenhead
Wirral
United Kingdom
CH49 5PE

Study participating centre
Barnsley Hospital
Gawber Road
Barnsley
United Kingdom
S75 2EP

Study participating centre
James Paget Hospital
Lowestoft Road
Gorleston-on-Sea
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Queen Elizabeth Hospital
Gayton Road
Kings Lynn
United Kingdom
PE30 4ET

Study participating centre
Hywel Dda University Health Board
Job's Well Road
Carmarthen
United Kingdom
SA31 3BB

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
University of Aberdeen/NHS Grampian
Research and Development Office
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Scotland
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AB25 2ZB

Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) - NIHR Health Technology Assessment Programme - HTA (UK) ref: 12/127/157

Results and Publications

Publication and dissemination plan
The dissemination plans include HTA monograph; presentation at international scientific meetings; and publications in high-impact open access journals; the results will be included in the updates of NICE and EAU (European Association of Urology) guidelines; these two specific guidelines directly influence practice in the UK and worldwide specialists respectively. In-addition, plain English language summary of the main findings/results will be presented for relevant patient organisations.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/08/2017		Yes	No
Results article		01/12/2022	16/12/2022	Yes	No
Other publications	Secondary analysis describing Aberdeen Home Continence Stress Test (HCST)	13/04/2023	14/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Patient preferences for stress urinary incontinence treatments: a discrete choice experiment	29/08/2023	30/08/2023	Yes	No