SIMS

Standard vs. Mini-Slings

PATIENT INFORMATION LEAFLET

The purpose of this study is to compare the effectiveness of Mini-Slings Versus Standard Slings in the Surgical Management of Stress Urinary Incontinence in Women

Web address: https://w3.abdn.ac.uk/hsru/sims/

INVITATION TO TAKE PART

We would like to invite you to take part in a research study comparing two surgical treatments for stress urinary incontinence. Before you decide if you would like to do so, it is important for you to understand why the research is being done and what it will involve.

Please take your time to read the following information carefully, discuss it with your family, friends, or G.P. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information.

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NHS National Institute for Health Research

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BACKGROUND

Stress urinary incontinence is the involuntary leakage of urine during effort, exercise, or simply coughing/ laughing etc. It may be caused by weakness in the supporting structures of the bladder and the bladder outlet (urethra).

One of the current standard surgical treatments for stress incontinence is the mid-urethral sling (MUS). MUS involves insertion of a special sling (mesh tape) underneath the bladder outlet. This mesh tape provides support to help prevent urinary leakage. The mesh tape is made of polypropylene mesh which is designed to be permanent after insertion. The procedure involves passing the mesh tape from the vagina to either the inner thigh or just behind the pubic bone to secure the mesh tape position. This requires the patient to have a general anaesthetic (i.e. put to sleep).

A new procedure, SIMS (Single Incision Mini-Slings), has recently been developed. This is a mini-version of the standard mesh tape. It uses the same type of mesh tape material; however it requires a single cut in the vagina, and is therefore less invasive.

WHAT IS THE PURPOSE OF THE STUDY

Doctors and patients groups agree that a large study is needed to compare the new minimal invasive procedure (SIMS) to the standard procedures. The study will inform surgeons, patients and decision makers about the most effective surgical treatment for stress urinary incontinence in women.

This UK-wide study will collect the views of 650 women over 3 years following their surgery to see if the two procedures get similar results. This will be done by evaluating the questionnaires completed by participating women over 3 years following surgery. The questionnaires will ask women relevant questions about their everyday experiences associated with bladder and sexual function.

The results of this study will enable us a) to decide the most effective surgical treatment for stress urinary incontinence that has the least impact on patients and b) assist the NHS to decide which is the surgical procedure that makes best use of the NHS and patient resources.

WHY HAVE I BEEN INVITED TO TAKE PART?

We are inviting you to take part in this study because you have been diagnosed with stress urinary incontinence and both you and your consultant have decided to proceed with surgical treatment in the form of a mesh tape procedure.

DO I HAVE TO TAKE PART?

It is entirely up to you whether or not you take part. Once you have read this information leaflet, ask your doctor (GP or hospital doctor) as many questions as you like, and also the research nurse who will be helping you at every stage of the study (if you decide to go ahead).

Whether or not you decide to take part in the SIMS study, you will receive the normal high standard of NHS care. You are also free to withdraw from the study at any time without giving a reason.

WHAT WILL HAPPEN IF I TAKE PART?

- Information and Consent:

The consultant in charge of your treatment or the local research team will give you full information about the study either in person or by sending you the information by post. If appropriate, a member of the local research team will discuss the study with you at the clinic or contact you by telephone to give you more information and answer any queries you may have.

After taking your time to consider the study and if you agree to take part you will be asked to sign a consent form.

- Before Surgery:

The local research team will provide you with a baseline questionnaire which can be done in the hospital or in the convenience of your home and returned in the pre-paid enveloped provided.

You will also be asked to do 2 simple tests, at your home, called the "pad test" and "home continence stress test" (you will receive an information sheet that explains these simple tests within the pack). You will not undertake any invasive examinations/ tests in this study.

If you agree, we will send you a text message reminder 48 hours before surgery to undertake these tests.

- **Type of Surgery:**

The particular treatment given to each woman in the study will be decided at random by computer. There is an equal chance of being placed into either group: the standard surgery group or the SIMS group. The surgeons participating in this national study are well trained in both of these procedures.

If you are in the SIMS group: we recommend that the procedure will be done under local anaesthesia (with possible oral sedation) to obtain the full benefit. You will be accompanied by a nurse at all times for support. However, if you wish to have general anaesthesia, your wishes will be fully respected and you can still participate in the study. If so please make your choice clear to your hospital doctor or the research nurse.

- **After Surgery:**

In the first 2 weeks: We will ask you to record your pain score every day on a paper diary provided to you. If you agree, we will text you to collect these scores by free text messages as well as the diary. We are aiming to find out if text messaging can replace paper pain diaries in future.

We will also use text messages to send you useful reminders about the Study.

At 4 weeks after the operation; you will complete the last section of your paper diary and send the completed diary by pre-paid post to the Study Office in Aberdeen.

At 3 months, 1 year, 2 years and 3 years: you will be sent a questionnaire similar to the one you completed at baseline. You will also be asked to repeat the “pad test” and “continence stress test” at home at 1, 2 and 3 years.

At approximately 20 months: we will send you a questionnaire to explore your views on the treatment you received and any personal expenses you may have incurred (e.g. hospital and/or GP visits.)

On return of your 3 month and yearly questionnaires we will send you a token of appreciation for your time spent on completing the questionnaires. Please let us know, on the consent form, if you don't wish to receive such a token.

Before Surgery

- You will be asked to complete a questionnaire about the problems caused by your incontinence and how it affects your life
- You will be asked to complete 2 simple tests at home "pad test" and "continence stress test"
- You will return the completed forms to the local research team on the day of the operation or by post to the Study Office using pre-paid post.

After Surgery

- At days 1-14 you will complete a diary recording any pain you have had.
- At 4 weeks you will complete a short questionnaire about your recovery period and satisfaction with your operation.
- You will then return the diary& questionnaire booklet to the Study Office using pre-paid post.

Later

- We will send you questionnaires by post at approximately 3, 12, 24 and 36 months after the operation to find out how you are progressing; how successful the operation has been and the impact it had on your quality of life.
- You will also be asked to repeat the "pad test" and "continence stress test" at home at 1, 2 and 3 years.
- We will also send you a questionnaire at 20 months which will ask about your views on the treatment you had and how much it cost you to attend any hospital and/or GP visits.
- You will send us the completed forms by pre-paid post.
- On return of your 3m and yearly questionnaires we will send you a token of appreciation for your time spent completing the questionnaires.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You may or may not benefit personally from taking part. By taking part, however, you will be directly helping us to inform the treatment of future patients with Stress Urinary Incontinence. The results of the study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE ADVANTAGES AND DISADVANTAGES OF TAKING PART?

The MHRA recently published a report on vaginal mesh implants and stated "MHRA's current position is that, for the majority of women, the

use of vaginal mesh implants is safe and effective."(MHRA report Nov 2014).

With the new procedure, SIMS, small studies that followed up patients for relatively short periods (1-2 years), have shown the following results:

- It is well tolerated under local anesthesia, which may make the operation potentially safer for patients.
- It results in earlier recovery, return to work and normal activities.
- It is less painful during and after the operation.
- Potentially equal success rate to the standard mesh tapes.

We do not think that there are any possible disadvantages or additional risks to you taking part in the study. Whichever group you are allocated to, your operation will be performed by a competent and trained surgeon. There are always risks associated with all operations and anaesthetics as explained in detail below and in the surgical leaflet about the different operations. Every effort is made to ensure that these risks are minimised.

The following information on possible risks (pages 11 to 15) is produced from the Scottish Government June 2014 publication: Synthetic Vaginal Mesh Mid-urethral Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women – Patient Information and Consent Booklet (this document is also available on the Scottish Government Website: www.scotland.gov.uk).

POSSIBLE RISKS OF THIS PROCEDURE

The tables below are designed to help you understand the risks associated with this type of surgery (based on the RCOG Clinical Governance Advice, Presenting Information on Risk). The terms used to denote the degrees of risk in the main table are explained here:

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a **family**
Common	1/10 to 1/100	One person in a **street**
Uncommon	1/100 to 1/1000	One person in a **village**
Rare	1/1000 to 1/10,000	One person in a **small town**
Very rare	Less than 1/10,000	One person in a **large town**

GENERAL RISKS OF SURGERY

Any surgical procedure has its risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** This is rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss with you in detail.

- **Bleeding:** You should expect some vaginal bleeding after the operation. The risk of major bleeding, which is severe enough to need a blood transfusion, is small but it can happen with any operation.
- **Infection:** The risk of infection at any of the wound sites is common, and you will receive antibiotics in theatre to reduce such risk. One in ten women will need a course of antibiotic to treat a urine infection. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.
- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following day-surgery (less than 1% of those who get a clot). However, there have been deaths following such clots and, therefore, special stockings and/or injection to thin the blood are provided to all patients.

SPECIFIC COMPLICATIONS AND RISKS*

Complication	Risk
Mesh exposure (erosion) into the vagina	**Common**. The vaginal skin over the sling may not heal properly or get infected. Could also be due to inflammation, foreign body reaction or unusual immune response. It can happen years after surgery. Further surgery may be required to cover the sling or to partly remove it (please see below).*
Recognised damage to the bladder or urethra during the procedure	**Common**, especially with the retropubic approach. When discovered during the procedure, the sling is removed and replaced

Complication	Risk
	correctly. Long term problems following this complication are unlikely.
Failure of the procedure to stop urine leakage	**Common**. Persistence or recurrence of urinary leakage after some time. This can happen years after the sling has been inserted even if it cured your symptoms originally. You may need further surgery for incontinence and success rates may be lower.
Problems with the need to pass water more often than normal or having trouble getting to the toilet in time	**Common**. Overactive bladder symptoms are managed with physiotherapy and/or drug treatment.
Temporary problems emptying bladder fully	**Common**. May require short-term home catheterisation (indwelling or intermittent) for few days or weeks.
Temporary pain in the pelvic area or at the site of the sling insertion (the groin area or inner thigh in transobturator procedure) or during sexual intercourse	**Common**. Often resolves spontaneously or with painkillers.
Chronic pain in the pelvic area, at the site of the sling insertion or during sexual intercourse (due to vaginal scarring)	**Common** with transobturator tape, affecting the groin area and/or inner thigh. Could be due to nerve damage/irritation. **Uncommon** with retropubic tape. Repeat procedures to remove the sling may be

Complication	Risk
	necessary (see below).*
Persistent problems emptying bladder fully with recurrent urinary tract infections	**Uncommon**. May require further surgery to release, cut or remove the sling.* Urine leakage may return and you may need further surgery.
Mesh extrusion (erosion) into the urethra or the bladder	**Rare**. This may lead to fistula formation and can occur years after surgery. Could be due to spontaneous sling displacement or unrecognised damage to the bladder or urethra during the procedure. Requires further surgery to remove the sling (see below).
Injury to other organs such as bowel and major blood vessels	**Rare**. An abdominal operation may be necessary to resolve the problem.
Chronic problems emptying bladder fully	**Rare**. May require long-term self-catheterisation for months/years.
Death	**Very rare**.

*The risk levels quoted are those reported in medical literature and confirmed/endorsed by the National Institute of Health and Clinical Excellence. Data from large relevant registries are not yet available at the time of writing this leaflet.

*RISKS IF THE MESH TAPE IS TO BE REMOVED

Repeat procedures may be necessary and complete sling removal may not be possible to do safely. Referral to a different hospital (with a mesh removal team) may be required and, even after complete removal, symptoms may persist. Partial or complete removal of the

mesh sling may result in the operation no longer working so you may need further surgery for incontinence.

FURTHER NOTES ON RISKS

- The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions, if you are over-weight or if you have previously had surgery for a similar problem.
- The National Institute for Health and Clinical Excellence has produced further information regarding the risks of vaginal slings in August 2013. You are able to access this using the following link: http://publications.nice.org.uk/urinary-incontinence-cg171/recommendations
- The Medicines and Healthcare products Regulatory Agency (MHRA) produced further information regarding the risks of vaginal slings in November 2012. You are able to access this using the following link: http://www.mhra.gov.uk – go to search box and type 'synthetic vaginal slings'.
- The sling is a synthetic **mesh permanent** implant and **it is strongly recommended you consider this procedure only after your family is complete**. There is an anticipated increased risk of failure following pregnancy and childbirth. Please discuss with your GP and surgeon if you intend to have more children.

(End of information from Scottish Government publication)

To make it easier, you can also access any of the above links on the study website (https://w3.abdn.ac.uk/hsru/sims/). However, if you require a printed copy of the information please contact the SIMS study office (contact details are on the last page of this leaflet).

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the study is stopped earlier than expected for any reason, you will be told and your continuing care will be arranged as per the standard clinical care from the NHS.

Once the study is completed, the results will be analysed and will inform the NHS on the best clinically effective and cost-effective procedure to be offered as primary surgical treatment for stress urinary incontinence in women.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. All procedures performed in this study are already being used in the NHS to treat patients with stress urinary incontinence.

However, if you believe that you have been harmed you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen. Sponsor contact details are available through the research team.

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS, which include professional indemnity insurance for negligence. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

If you become unable (for any reason such as severe un-related illness) or unwilling to continue in SIMS we would withdraw you from the study. A member of the research team will contact you by mail/telephone and complete a “change of status form” which includes your instructions on what parts, or whole, of the study that you may wish to withdraw from. We will keep the relevant information already collected about you up to that point, for the study results. This

information will remain confidential and will not be used for any other purpose.

If you have private medical insurance you should check with the company before agreeing to take part in the study. We do not know of a reason, however, why participation might affect your medical insurance.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the Patient information leaflet (PIL) may be updated, as has happened with the new information from the MHRA report and the Scottish Government publication included in this updated version of the PIL. The SIMS Study Office staff may contact you to let you know about the new information and if any action needs to be taken. We will also use the study website to keep you updated.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential, and will only be seen by those who have a "need to know". It will be held securely in accordance with the Data Protection Act 1998.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.
We will tell your GP you are taking part, but only with your permission.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with Stress Urinary Incontinence. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The research is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme i.e. NHS funded. This study is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT); a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been approved by the North of Scotland Research Ethics Committee.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and the Research & Development Department of your local hospital, whose roles are to check this research is properly conducted and the interests of those taking part in this study are protected.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the SIMS study. Please ask us if you have questions or would like more information about the study.

INDEPENDENT CONTACT

If you would like further information on the study from an independent contact, the SIMS study office can put you in touch with the Chair of the Independent Steering Committee.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

SIMS Study Office,
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Local Centre contact details:

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