Prospective Registry for Patients Undergoing Artificial Urinary Sphincter Surgery for Female Stress Urinary Incontinence due to intrinsic sphincter deficiency. EAU-RF 2019-01 (VENUS)

Goal and Design

To set up a Registry database for female patients undergoing AUS implantation surgery (Robot-assisted, Laparoscopic, Open or other) for stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD).

To provide insight in the daily clinical practice of the AUS implantation treatment and short- and long-term follow-up outcome (efficacy, complications, quality of life, urodynamic parameters, sexual function) of patients treated for SUI due to ISD.

Study Outcome

Main outcome:

Main outcome for this registry will be the cure rate of AUS implantation surgeries for treatment of female SUI due to ISD. Cure rate is defined as urinary continence with no pads used or use of 1 light security pad.

Other outcomes:

- Time being incontinence-free
- The results of the Questionnaires (ICIQ-UI-SF, ICIQ-FLUTSsex, ICIQ-LUTSqol, PGI-I), and the 24-hour pad tests, and cough stress tests at each of the evaluation points during follow-up.
- The change of results of Questionnaires (ICIQ-UI-SF, ICIQ-FLUTSsex, ICIQ-LUTSqol, PGI-I), and the 24-hour pad tests, and cough stress tests as compared with baseline over time.
- The change of urodynamic parameters at Week 12 compared with baseline.
- The change of uroflowmetric parameters (maximum free urinary flow, Post void Residual Volume) at each of the evaluation points during follow-up compared with baseline.
- Postoperative symptoms and complications.
- Revision free rate at specific time points and time being revision-free. A revision is defined as any urogenital surgical intervention that is related to the function, placement, or site reaction to the implanted device.
- To perform a prognostic factor analysis to identify clinical and surgical variables for each of the AUS implantation surgery procedures (Robot-assisted, Laparoscopic, Open, or other) that correlate with patient-reported scores on Urinary Incontinence, sexual function and QoL, complications and revisions for the AUS device.

Study Participants

Female patients undergoing AUS implantation surgery (Robot-assisted, Laparoscopic, Open or other) for treatment of stress urinary incontinence due to intrinsic sphincter deficiency.

Patient Inclusion Criteria
1. The patient should be Female and aged 18 years or older.
2. The patient will undergo an initial AUS implantation surgery (Robot-assisted, Laparoscopic, Open or other) for treatment of stress urinary incontinence due to intrinsic sphincter deficiency.
3. The patient is willing and able to give written informed consent for participation in the Registry.
4. The patient is able to complete the questionnaires.

The centre may participate in the study if the centre is able to contribute consecutive patients.

Registry procedures

Registry visits for patients undergoing surgery for stress incontinence are typically conducted before surgery, and after the surgical procedure at 6 weeks (activation of AUS), 12 weeks and 1 year post-surgery. These visits will be the minimum anticipated follow up requirements in the protocol. Long term follow-up will consist of yearly visits after visit at one-year post-surgery until at maximum year 5.

Study assessments

Study assessments will be undertaken at the local centres as per local arrangements.

⇒ Pre-operative data: Patient characteristics, Coexistent pelvic organ prolapse, Previous treatments of stress incontinence, Main cause of stress incontinence, Medical History, The Charlson Comorbidity Index and physical examination, 24-hour pad test, Pinch/Ulmsten test, pre-operative urodynamic results, cough stress test and main conclusion of the urodynamic investigation and uroflowmetry, If available, cystoscopy or any other relevant investigations, presence of pre-operative urinary tract infections (UTI). The use of antiseptic washings and if the patient received pre-operative antibiotics will also be reported. Patient-reported results of the Questionnaires (ICIQ-UI-SF, ICIQ-FLUTSsex, ICIQ- LUTSqol)

⇒ Per-operative data: type of surgery, type of prosthesis, surgical approach, date and duration of surgery, surgeon ID, pump location, cuff size, pressure of regulating balloon (cm H_2O), filling solution, type of associated procedures, type of per-operative antibiotics, use of suprapubic or transurethral catheter or drain, complications during surgery

⇒ Post-operative data: Length of hospital stay, post-operative pain, use of analgesics and antibiotics, Uroflowmetry, Complications, Revisions, activation problems, questionnaires

Please find the full description of the registry on the ClinicalTrials.gov website:
https://clinicaltrials.gov/ct2/show/NCT04114266

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