

Prospective Registry for Patients Undergoing Penile Prosthesis Implantation for Male Erectile Dysfunction. EAU-RF 2018-01 (PHOENIX)

Design and goal

This will be a prospective collection of pre-defined parameters on the surgical treatment of male erectile dysfunction using penile prostheses implant (PPI) devices.

To provide insight in daily clinical practice regarding the indication for surgical treatment, the choice of the type of prosthesis, and short- and long-term follow-up outcome (efficacy, morbidity, complications, quality of life, patient- and partner satisfaction score) of patients treated with a variety of PPIs.

Study Outcomes

Main outcome:

Patient Satisfaction score at 12 weeks and year 1 and 2 after implantation and subsequently at 2-yearly intervals during follow-up until the end of registry (10 years after enrolment of the first patient). Satisfaction score is defined as the mean patient satisfaction score as indicated by the Modified Patient EDITS Questionnaire.

Other outcomes:

- ◇ Partner Satisfaction score.
 - ◇ Patient and Partner Satisfaction rate as indicated by the number of patients/partners with an EDITS score of ≥ 50 compared to the total number of patients/partners at each of the evaluation points during follow-up.
 - ◇ Overall time the patient is satisfied with treatment since implantation.
 - ◇ The results of the IIEF-5, SEP 2 and 3, satisfaction questions and EQ-5D-5L and QoLSPP questionnaires.
 - ◇ Postoperative symptoms possibly related to the surgical procedure or the prosthesis.
 - ◇ Postoperative specific complications related to the surgical procedure or prosthesis.
 - ◇ Time of first activation, first cycling, first use, first intercourse, first orgasm (if applicable).
 - ◇ Revision free rate at specific time points and time being revision-free.
 - ◇ To determine other post-operative outcomes of surgical treatment of erectile dysfunction for each of the penile implant devices and to perform a prognostic factor analysis to identify clinical and surgical variables that correlate with patient satisfaction score, complications and revisions for each of the device subtypes.
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Study Participants

A total of 1000 male patients undergoing a surgical penile prosthesis implantation for treatment of erectile dysfunction.

Registry procedures

Registry visits for patients undergoing surgery for erectile dysfunction with PPIs are typically conducted before surgery, and after the surgical procedure at 4-6 weeks, 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 a visit 2 years post-surgery and subsequently 2-yearly visits until the end of registry, 10 years after the first patient was enrolled.

Study assessments

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

- ⇒ Pre-operative data (e.g. patient characteristics, Charlson co-morbidity index, previous treatments for ED (such as oral drugs, ICIs, vacuum device, shock wave treatment), surgical treatment or radiotherapy in pelvic/abdominal area)
- ⇒ Peri-operative data (e.g. details on infection preventative measures, surgery, type of PPI, length of prosthesis, type of associated procedures (e.g. curvature management), type of per-operative antibiotics, use of suprapubic or transurethral catheter or drain)

Please find the full description of the registry on the ClinicalTrials.gov website: <https://clinicaltrials.gov/ct2/show/NCT03849586>

Sponsor:

European Association of Urology Research Foundation

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