Prospective Registry for Patients Undergoing Surgery for Male Stress Urinary Incontinence in Multiple European Centres. EAU-RF 2016-01 (SATURN)

Design and setting

This is a prospective data collection on 2 main surgical interventions using medical devices such as AUS and male slings for the treatment of stress urinary incontinence in males.

We are collecting prospective data from multiple centres in Europe to evaluate the short and long term efficacy and complications of these procedures along with impact on Quality of Life.

Study Objectives

- *Primary objective:*
  To evaluate the cure rate of procedures for treatment of male stress urinary incontinence during study follow up. Cure rate will be the main endpoint of the study, and is defined as urinary continence with no need for use of pads or the use of 1 light security pad. The cure rate during study follow up will be calculated together with its 95% Confidence Intervals, for the total patient group as well as for each device subtype. A revision is defined as any urogenital surgical intervention that is related to the function, placement, or site reaction to the implanted device.

- *Secondary objectives and endpoints*:
  To determine other outcomes of surgical treatment of male stress urinary incontinence for each of the devices and to perform a prognostic factor analysis to identify clinical and surgical variables that correlate with (in)-continence or revisions for each of the device subtypes.

Secondary endpoints that will be evaluated are:

- Time being incontinence-free defined as the interval from the date of regaining continence after surgery to the date of incontinence recurrence. Patients who die will be censored at time of death. Overall time of being incontinence free will be presented using the Kaplan-Meier curve, for the total patient group as well as for each device subtype.
- Time being revision-free defined as the interval from the date of surgery to the date of revision. Patients who die will be censored at time of death. Overall time being revision-free will be presented using the Kaplan-Meier curve, for the total patient group as well as for each device subtype.
- Revision-free rate during study follow-up.
- Safety. Number of patients with complications such as: urinary retention, scrotal hematoma, perineal pain, hematuria, or other local or general problems will be presented in a tabular format.
- Change in quality of life compared with baseline (pre-surgery) will be reported at week 12, year 1, and then yearly up to and including year 10.
- Change in the results of the incontinence questionnaire versus baseline (pre-surgery). The change in the results of the incontinence questionnaire compared with baseline (pre-surgery) will be reported at week 12, year 1, and then yearly up to and including year 10.
- Number of patients with postoperative specific events related to the surgical procedure or the sling / prosthesis (e.g. pump/reservoir/cuff failure, erosion of the device through the skin or urethra).

Study Participants

A total of 1000 male patients undergoing surgery for treatment of stress urinary incontinence with medical devices such as AUS or sling in a given centre.

Study Status

As of press time (cut-off date March 1st 2020), twenty-four centres are initiated of which 22 sites recorded in total 587 patients in the eCRF. This may be an underestimation of the actual number of recruited patients as not all included patients are yet recorded in the eCRF.

Nr.	(Sub) Investigator	City	Hospital	Date EC Approval	# Patients recorded in eCRF
NL-01	J. Heesakkers/ F. Martens	Nijmegen	Radboud UMC	Oct-2016	97
ES-01	E. Pascual/ I. Salamanca	Madrid	UH P. de Hierro Majadahonda	Jun-2017	22
CZ-01	R. Zachoval/L. Bartáková	Prague	Thomayer Hospital	Jun-2017	39
BE-01	F. Van der Aa	Leuven	UHs Leuven	Sep-2017	145
NL-02	L. de Kort	Utrecht	UMC Utrecht	Jan-2018	35
DE-01	A. Haferkamp	Mainz	UH Mainz	Oct-2017	3
GB-01	R. Hamid	London	Royal National Orthopaedic Hospital	Mar-2018	7
ES-03	M. Castro Diaz	Tenerife	HU de Canarias	Apr-2018	15
ES-02	J. Romero-Otero	Madrid	HU 12 de Octubre	Jun-2018	33
GB-02	N. Thiruchelvam	Cambridge	CUH - Addenbrooke's Hospital	Mar-2018	16
NO-01	O-J. Nilsen	Oslo	Oslo UH	Dec-2017	82
BE-03	K. Van Renterghem	Hasselt	Jessa Ziekenhuis	Jul-2018	30
BE-02	K. Everaert	Gent	UH Gent	Jul-2018	9
ES-04	I. Puche-Sanz	Granada	HU Virgen de las Nieves	Nov-2018	4
IT-01	M. Tutolo	Milan	San Raffaele	Aug-2018	-
IT-03	E. Sacco	Rome	FPU Agostino Gemelli IRCCS	Aug-2019	16
ES-05	C. Ochoa V.	Barcelona	HU Germans Trias i Pujol	Dec-2018	12
ES-06	E. Lledó	Madrid	HU Gregorio Marañón	Feb-2019	2
IT-02	G. Bozzini	Busto Arsizio	ASST Valle Olona	Mar-2019	-
DE-02	F. Queißert	Münster	Universitätsklinikum Münster	Mar-2019	1
BE-04	S. Van Bruwaene	Kortrijk	AZ Groeninge	Mar-2019	5
ES-07	S. Arlandis	Valencia	University Hospital La Fe	Apr-2019	8
DE-03	M. Fisch	Hamburg	Universitätsklinikum Hamburg-Eppendorf	Apr-2019	3
ES-08	A. Fraile Poblador	Madrid	Hospital Universitario Ramón y Cajal	Feb 2020	3
					587

Please find the full description of the registry on the ClinicalTrials.gov website:
https://clinicaltrials.gov/ct2/show/NCT02757274

Sponsor:
European Association of Urology Research Foundation

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