Calistar A vs. Calistar S - Comparative Cohort Retrospective Analysis of Single Incision POP Systems

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Version number: Ver_03

Date: 28/05/2018

NCT03715803

Study Protocol

CALISTAR A VS CALISTAR S – COHORT RETROSPECTIVE ANALYSIS

(Ver_03 – 28/05/2018)

PROTOCOL APPROVAL

_____ _____

Responsible/Protocol Author/PI *(dd/mm/yyyy)*

This protocol has been designed in accordance with the principles of Good Clinical Practices, EN-ISO 14155, Declaration of Helsinki and other applicable regulatory requirements.

SIGNATURE PAGE

CALISTAR A VS CALISTAR S – COHORT RETROSPECTIVE ANALYSIS

(Ver_03 – 28/05/2018)

I have read this protocol and agree to adhere to the requirements. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision and my hospital ethics committee / institutional review board (EC/ORB). I will discuss this material with them and ensure they are fully informed regarding the device and the conduct of the study according to this protocol, applicable laws, and applicable regulatory requirements including Good Clinical Practices.

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Clinical Site Name

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Site Principal Investigator Signature Date

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Site Principal Investigator Printed Name

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GENERAL INFORMATION

Protocol ID	
Short title	CALISTAR A VS CALISTAR S – Cohort retrospective analysis
EudraCT number	N/a
Version	3.0
Date	28/05/2018
Coordinating investigator/project leader	Dr. A. Sampietro, Gynecologist Hospital Universitario Austral, Department of gynaecology Av. Juan Domingo Perón 1500, Pilar Centro, Buenos Aires, Argentina + 54-230-448-2163 asampietro@live.com.ar
Principal investigators	**See Annex 1**
Sponsor	N/a
Product	Calistar A and Calistar S Single Incision POP System from Promedon. The products which are the object of this study have the approval according the CE-Guideline 93/42/EWG.
Objective	To compare the initial outcomes and complication of a high weight and a low weight meshes, Calistar A and Calistar S, respectively, implanted through a single incision to treat anterior and apical prolapses.
Study design	Multicentre, post-market, retrospective, two arms, non-randomized comparative study.
Study population	Adult female
Main study parameters/ primary endpoints	Effectiveness of Calistar S and Calistar A will be assessed by cure criteria of Barber, that is: - Lowest point of POP-Q < 0 (no points beyond the hymen) - No subjective bothersome symptoms (absence of vaginal bulge symptoms) - No re-treatment/interventions on year post procedure.

Secondary endpoints	The secondary endpoint is defined as the objective assessment of POP by POP-Q. POP-Q staging will be compared pre- and post-operative. The subjective outcome is defined as the assessment of subjective symptoms resulting from POP by validated quality of life (QoL) questionnaires (improvement of the QoL of the subjects compared to the baseline values): - Pelvic Floor Distress Inventory (PFDI 20) to assess the impact of urinary, prolapse and colorectal distress post-operative. - Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire (PISQ-12) to evaluate sexual function in women with pelvic organ prolapse and/or urinary incontinence post-operative. - Patient Global Impression to evaluate patient satisfaction with the experience and the result of procedure. Type of surgery and operative time will be compared for both pelvic floor systems repair.
Safety endpoints	Operative complications such as bladder injury and blood loss will be evaluated. Complications related to the use of meshes such as vaginal pain, infection and mesh erosion will be assessed.
Inclusion criteria	Female; Anterior and apical prolapse Stage 3 (according to POP-Q) or more with or without SUI; Primary or recurrent treatment with Calistar S or Calistar A; At least 6 months follow-up
Exclusion criteria	Recurrent vaginal infections; Chronic colorectal diseases (chronic nonspecific ulcerative colitis, diverticulitis, diverticulosis, Chron's disease, irritable bowel syndrome, familial polyposis); Presence of any coagulopathies; Impairment of the immune system or any condition that compromises recovery; Prior irradiation; Chronic pelvic pain

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