Mid-term evaluation of the efficacy and safety of the Calistar S pelvic floor repair system for prolapse repair.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20957

Source
Nationaal Trial Register

Brief title
Calistar S Safety & Efficacy

Health condition

Pelvic Organ Prolaps
Anterior and/or apical Prolaps
Cystocele

Bekkenbodem verzakking
Anterieure en / of apicale verzakking
cystocele

Sponsors and support

Primary sponsor: Promedon GmbH
Source(s) of monetary or material Support: not available yet

Intervention

Outcome measures

Primary outcome

Cure according to Barber criteria (that means meeting 3 conditions: 1: lowest point POP ≤ 1, 2: no subjective bothersome symptoms (PFDI Questionnaire), 3: no re-intervention) one year post procedure.

Secondary outcome

To evaluate objective and subjective variables of the implantation (e.g. operating time, surgical performance), mid-term safety (e.g. adverse events) and outcomes (e.g. sexual function).
1. Quality of Life (QoL-Status)
2. Operation Time
3. Rate of the vaginal erosion because of the Calistar S mesh insertion.
4. Frequency, beginning and type of new or worsening urinary incontinence
5. Interval POP-Q Staging
6. Indication of pain in the pelvic area associated with the performed mesh insertion
7. Satisfaction of the subjects
8. Frequency of the necessary surgical revisions of the Calistar S mesh implant

Study description

Background summary

Background of the Study:
The surgical treatment of pelvic organ prolapse has significantly evolved over the last few decades due to increased understanding of the anatomy as well as the development of minimally invasive surgeries.
For the treatment of POP different surgical approaches are available. One treatment option are vaginal implants, which are used in the anterior or posterior vaginal wall, to induce a foreign body response. Vaginal meshes also suspends the apex by a bilateral suspension of the vaginal vault or cervix to both sacrospinous ligaments. Within this study the efficacy and safety of one specific mesh is evaluated.

Aim of the Study:
This prospective, single-arm study is to evaluate the mid-term efficacy and safety of the Calistar S pelvic floor repair system for prolapse repair.

Study objective

The type of implanted meshes has evolved steadily over the past few years in terms of material and fixation method. At the beginning, mainly fine-pored meshes (pore size <3 mm)

with a high basis weight (up to 60 g / m2) and a 6-point fixation were implanted, nowadays mostly large-pored and flexible meshes (pore size> 6 mm) with a low basis weight (up to 16 g / m2) and a 4-point fixation. These properties are expected to result in better tissue ingrowth and lower interaction with the natural tissue, resulting in better anatomical and functional results and lower complication rates. A look at the current guideline shows that all available prospective studies are done by using older products that are not part of the latest generation of meshes. Therefore, it is of great benefit and interest in medical research to understand the complication and recurrence rates of such meshes (in this case, Calistar S) in a study. The latest scientific findings on prolapse surgery are also an important element in the further development of guidelines.

Study design

Pre Procedure

6-8 Weeks
6 Months
12 Months
24 Months

Intervention

Implantation of Calistar S Mesh for anterior and apical or anterior prolaps repair

Contacts

Public
Promedon GmbH
Martina Mayr

00498031900400
Scientific
Promedon GmbH
Martina Mayr

00498031900400

Eligibility criteria

Inclusion criteria

To be eligible to participate in this study, a subject must meet all of the following criteria:

| 1. Subject is female
| 2. Post-menopausal status of the subject
| 3. Subject has documented diagnosis of anterior or anterior and apical vaginal prolapse with leading edge of pelvic organ prolapse at or beyond the hymen. At or beyond the hymen is defined as POP-Q scores of Ba ≥ 0; or Ba ≥ 0 and C ≥ -1/2 TVL.
| 4. Both subjects with primary and secondary cases are eligible for the study. In case of primary occurrence of prolapse subjects must at least fulfill two risk criteria according to the current IUGA recommendations (listed in point 10.2.2.1. of the protocol).
| 5. Subject should report bothersome or very bothersome prolapse symptoms (PFDI Question 3 ≥ 2)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

| 1. Subject has had a prior prolapse implant / procedure (graft augmented repair) (previous sling therapy is allowed)
| 2. Subject has active or latent systemic infection or signs of tissue necrosis.
| 3. Subject is currently pregnant or intends to become pregnant in the future.
| 4. Subject has had radiation therapy to the pelvic area.
| 5. Subject is on any medication which could result in compromised immune response, such as immune modulators and antirheumatic medication.
| 6. Subjects who are not capable of giving informed consent;
| 7. Subject has a known sensitivity to polypropylene;
| 8. Subject has an indication for a concomitant procedure to treat SUI;
| 9. Subject is known with pelvic organ cancer (e.g. uterine, ovarian, bladder or cervical);
| 10. Subject has chronic systemic pain that includes the pelvic area or chronic focal pain that involves the pelvis;
| 11. Subject has a known neurologic or medical condition affecting bladder function (e.g. multiple sclerosis, spinal cord injury or stroke with residual neurologic deficit).
| 12. Subject is undergoing anticoagulant therapy (The anticoagulant medication should be discontinued / bridged for the operation in accordance with the hospital guidelines)

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	165
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7642
Other	METC AMC : clinicaltrials.gov - NCT03821142

Study results

Summary results
no publications yet