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

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20957

Bron
NTR

Verkorte titel
Calistar S Safety & Efficacy

Aandoening

Pelvic Organ Prolaps
Anterior and/or apical Prolaps
Cystocele

Bekkenbodem verzakking
Anterieure en / of apicale verzakking
cystocele

Ondersteuning

Primaire sponsor: Promedon GmbH
Overige ondersteuning: not available yet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Pre Procedure

6-8 Weeks
6 Months
12 Months
24 Months

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	165
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

no publications yet