Prospective, multicenter, 36 months, comparative matched cohort study to evaluate the efficacy and safety of the ultra-lightweight mesh CAlistar S in transvaginal Pelvic Organ Prolapse repair

Published: 25-05-2021
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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON54988

Source
ToetsingOnline

Brief title
Calistar S in transvaginal Pelvic Organ Prolapse repair

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
anterior Prolaps, Cystocele

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Promedon GmbH

Intervention

Keyword: Calistar S, Cystocele, Mesh, Prolaps

Outcome measures

Primary outcome

Surgical success according to

1: lowest point POP <= 1,

2: no subjective bothersome symptoms (PFDI Questionnaire),

3: no re-intervention) in the respective compartment.

Secondary outcome

Secondary Endpoints:

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

9. Adverse events / complications.

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.

Study objective

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 design

Studydesign:
This is a prospective, single-arm, multicenter study which is based on the protocol. Within this study it is planned to include 179 Dutch patients which are undergoing the POP-Treatment with Calistar S Prolapse Repair System.

Intervention

Calistar S for transvaginal pelvic organ prolapse repair.

Study burden and risks

The cumulative success after prolapse surgery in which a synthetic mesh is implanted, is 93%. See chapter 10.3 of the protocol for more information.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Women >= 18 years old
2. Postmenopausal status and / or post-hysterectomy and / or sterilised
3. Either anterior or combined anterior and apical vaginal prolapse according POP-Q
score >= 2. Corresponding to Ba >= -1; or Ba >= -1 and C >= -1/2 TVL.
4. Subjects with recurrent prolapse as well as primary prolapse with high risk for
recurrence are eligible for the study.
5. Subject should be symptomatic regarding pelvic organ prolapse

Exclusion criteria

1. History of pelvic implant (biological graft or mesh augmented repair) (Prior suburethral
sling for treatment of stress urinary incontinence is allowed)
2. Local or systemic active or latent infection and/or signs of tissue necrosis
3. Current pregnancy or planned pregnancy (no completion of family planning)
4. History of pelvic radiation therapy
5. Immune compromised or medication which could result in compromised immune response (e.g. immune modulators, antirheumatic medication)
6. Sensitivity/Allergy to polypropylene
7. Intended simultaneous procedure to treat stress urinary incontinence
8. Current or history of pelvic organ cancer (e.g. uterine, ovarian, bladder or cervical);
9. Presence of chronic pelvic pain syndromes or other systemic pain syndromes (e.g.
fibromyalgia)
10. Presence of neurologic or medical condition affecting urinary bladder function (e.g.
Multiple sclerosis, spinal cord injury, stroke with residual neurologic deficit, etc)
11. Current anticoagulant therapy which can not be temporarily bridged or stopped
12. Ulcus of the vaginal wall.
13. Subject is unable or unwilling to complete questionnaires (either self-administered,
assisted or interviewed) and/or to follow scheduled visits and/or to sign informed
consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2021

Enrollment:	179
Type:	Actual

Medical products/devices used

Generic name:	Calistar S
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL69695.100.20
Other	NL9815