Prospective long-term evaluation of the performance and safety of Calistar S for transvaginal pelvic organ prolapse repair

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28804

Source
Nationaal Trial Register

Brief title
Calistar S

Health condition

Female Pelvic Organ Prolapse

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Industrie/Bedrijf

Intervention

Outcome measures

Primary outcome

Number of patients with surgical treatment success of anterior and apical pelvic organ prolapse after 24 months

Secondary outcome

Quality of life, sexual function, complication rates, revision and explantation free survival, surgical treatment for urinary stress incontinence, cure in short, mid-term, and long-term follow-Up.

Study description

Background summary

This is a prospective, long-term, multicenter comparative matched cohort study to evaluate the efficacy and safety of the Calistar S pelvic Floor repair system in women undergoing transvaginal POP repair.

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

Long-term evaluation of the efficacy and safety of the Calistar S pelvic floor repair system for the transvaginal The purpose of this investigation is the evaluation of the performance and safety of Calistar S in women with anterior POP with or without apical vaginal wall involvement in both, recurrent POP or primary complex POP as compared to control group of women treated with Restorelle mesh.

Study design

Baseline
6-Week Follow-UP
6-Month Follow-UP
12-Month Follow-UP
24-Month Follow-UP
36-Month Follow-UP

Intervention

Calistar S for transvaginal pelvic organ prolapse repair

Contacts

Public
AMC
Gert-Jan van Baaren

0205669111
Scientific
AMC
Gert-Jan van Baaren

0205669111

Eligibility criteria

Inclusion criteria

1. Non-pregnant women > 18 years defined by postmenopausal status and / or iatrogenic causes which exclude women permanently from becoming pregnant (e.g. history of hysterectomy or sterilised women).
2. Anterior prolapse with or without apical vaginal wall involvement according POP-Q score ≥ 2
3. Subjects with recurrent prolapse as well as primary complex prolapse when other surgical procedures are expected to fail (i.e. high risk for recurrence) are eligible for the study.
4. Scheduled mesh-augmented anterior POP repair with Calistar S

Exclusion criteria

1. Pregnant women
2. Patients with active or latent infection of the vagina, cervix or uterus
3. Patients with previous or current vaginal, cervical or uterine cancer
4. Previous, current or planned pelvic radiation therapy
5. Known allergy to polypropylene
6. Ulcus of the vaginal wall
7. 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2021
Enrollment:	179
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-10-2021
Application type:	First submission

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	NL9815
Other	MEC-U : R20.013

Study results