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

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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...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28804

**Bron**
NTR

**Verkorte titel**
Calistar S

**Aandoening**

Female Pelvic Organ Prolapse

### Ondersteuning

**Primaire sponsor:** AMC
**Overige ondersteuning:** Industrie/Bedrijf

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

Calistar S for transvaginal pelvic organ prolapse repair

# Contactpersonen

## Publiek

AMC
Gert-Jan van Baaren

0205669111

## Wetenschappelijk

AMC
Gert-Jan van Baaren

0205669111

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# 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: | 01-12-2021 |
| Aantal proefpersonen: | 179 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 25-10-2021 |
| Soort: | Eerste indiening |

# 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 | NL9815 |
| Ander register | MEC-U : R20.013 |

# Resultaten