A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the GYNECARE PROLIFT +M* Pelvic Floor Repair System as a Device for Pelvic Organ Prolapse

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The primary objective of this study is to evaluate the anatomical success of the GYNECARE PROLIFT + M* system in women with symptomatic ICS POP-Q Stage III or IV, requiring surgical correction of pelvic organ prolapse (POP). Secondary objectives...

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

Summary

ID

NL-OMON31625

Source
ToetsingOnline

Brief title
The GYNECARE PROLIFT

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Ethicon_Johnson & Johnson Medical Ltd
Source(s) of monetary or material Support: Ethicon;Johnson & Johnson

Intervention

Keyword: Mesh, Pelvic organ prolapse (POP)

Outcome measures

Primary outcome

There will be one primary effectiveness end-point:

* POP-Q score at 12 months post-procedure. Success will be determined by achievement of a POP-Q score of ICS Stage *1, without further surgical re-intervention for POP.

Secondary outcome

* Summary of ICS Stages at 3 and 36 month visits.

* Summary of treated compartment ICS POP-Q stage at 3, 12 and 36 months.

* Proportion of subjects with the leading edge within the hymen (i.e. all POP-Q values to be less than 0) and without further re-intervention for POP at 12 and 36 months.

* Mean scores and change from baseline in PFDI-20 scores at 3, 12 and 36 month visits including sub scores (POPDI, CRADI and UDI).

* Proportion of subjects with a change from baseline * 45 points in the PFDI-20 summary score at 12 and 36 months.

* Mean scores and change from baseline in PFIQ-7 at 3, 12 and 36 month visits including sub-scores (POPIQ, CRAIQ and UIQ).

* Proportion of subjects with a change from baseline * 36 points in the PFIQ-7

summary score at 12 and 36 months.

* Days to return to normal activities (walking, driving, work, household activities and sexual intercourse).

* EuroQol (EQ-5D health state) mean change from baseline at 3 and 12 months visit (overall using the EQ-5D index score, and also for each individual item).

* In subjects sexually active at baseline, assessment of sexual function using PISQ-12 assessed at 12 and 36 month visits (mean scores and change from baseline).

* Incidence of new onset dyspareunia, resolution or continuance of pre-existing dyspareunia

* Incidence of mesh contraction, as determined by pain on palpation of mesh during pelvic examination at 3, 12 and 36 months.

* Incidence of vaginal wall stiffness, as determined by the investigator on physical examination at 3, 12 and 36 months.

* Total time in the operating room.

* Length of procedure (from time of first incision to time of last suture).

* Nights in hospital (from date of admission to date of discharge; based on actual data and *readiness for discharge*).

* Pain score 24 hours post surgery and at the 1 month visit, measured using Visual Analog Scale (VAS).

* Subject global impression assessed on a 5 point Likert scale at 3, 12 and 36-month visits.

* Surgical satisfaction question assessed at 3 and 12 month visits.

Study description

Background summary

The Clinical Investigator Brochure summarises the technical, pre-clinical and clinical information available to support the clinical investigation of GYNECARE PROLIFT+M* Pelvic Floor System. Many women with Pelvic Organ Prolapse POP seek an alternative to non-surgical interventions of pelvic floor exercises and pessary support. Synthetic meshes have been used with increasing frequency in gynecologic surgery over the past 30 years. These synthetic meshes have been demonstrated to be an effective alternative treatment for POP.

Currently the GYNECARE PROLIFT Pelvic Floor System is licensed and marketed in Europe for the treatment of POP. Whilst successful anatomical results are being reported following the placement of the device, there is a need to reduce the incidence of mesh-related complications such as mesh retraction and stiffness leading to pain, including dyspareunia. Replacing the existing polypropylene mesh (GYNECARE GYNEMESH PS) with a lighter weight composite mesh (GYNECARE GYNEMESH M), it is anticipated that there will be reduction in these symptoms. Therefore, the purpose of this study is to evaluate the clinical performance of the PROLIFT+M system in women with symptomatic ICS POP-Q Stage III or IV, requiring surgical correction of POP.

Study objective

The primary objective of this study is to evaluate the anatomical success of the GYNECARE PROLIFT + M* system in women with symptomatic ICS POP-Q Stage III or IV, requiring surgical correction of pelvic organ prolapse (POP).

Secondary objectives include the evaluation of patient reported outcomes (PFDI-20, PFIQ-7, PISQ-12, Euro-QOL), length of procedure, length of hospital stay, post-operative pain, return to normal activities, and peri- and post-operative complications.

Study design

This study is a prospective, multi-centre, single-arm design. Subjects will be assessed prior to surgery, during and after the procedure, and at 1, 3, 12 and 36 months post-procedure.

Intervention

GYNECARE PROLIFT.

Study burden and risks

Risk & Benefit Assessment
The GYNECARE PROLIFT+M systems are indicated for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect. Clinical studies have shown the system provides improvement in stabilization of vaginal prolapse. Reported adverse events for this device urinary tract infection, urinary incontinence, voiding dysfunction, vaginal
atrophy, mesh exposure, anterior prolapse, pain, and dyspareunia.

Potential Benefits of GYNECARE PROLIFT+M Systems:
The device is intended for surgical repair of pelvic floor prolapse. Through a transvaginal approach, gynecologists can offer a treatment option with the following possible benefits and advantages.
1. Reinforcement of weakened tissue, suspension of unsupported structures or a combination of both.
2. Offers a minimally invasive treatment.
3. Presents a minimal number and degree of observed adverse events from prior clinical experience.
4. Provides an alternative treatment option for physicians and their patients.

Urogynecologists are the primary practitioners in the medical care of women with pelvic floor prolapse. Gynecological procedures for the treatment of pelvic floor prolapse are associated with certain risks. These risks are outline in section 10 of the protocol. Additionally, there are potential risks that may be directly associated with the device. These risks are as follows:

Potential Risks of GYNECARE PROLIFT+M Systems
Mesh exposure is a common complication, which can be managed by excision and closure. Mesh retraction ("shrinkage") is less common but is considered more serious than mesh exposure. It can cause vaginal anatomic distortion with pain, which may also have a negative impact on sexual function. The scar plate that forms with in-growth of tissue into the mesh can cause stiffness in the vagina that can further impact sexual function in a negative manner.

In an effort to minimize mesh retraction and reduce mesh stiffness, the GYNECARE GYNEMESH M Mesh is being studied.

Conclusion
Clinical experience with the Prolift system has demonstrated promising anatomical results with improvements in POP-related symptoms. Overall, complications are low, but generally related to the mesh. In order to improve the device, a lighter-weight mesh has been introduced into the system and this will be evaluated in the proposed clinical study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Candidates with symptomatic pelvic organ prolapse of ICS POP-Q Stage III or IV, suitable for surgical repair. Perineal repair, vaginal hysterectomy and/or mid urethral sling procedures for incontinence may be performed concurrently.
2. Age ><= 18 years.
3. Agrees to participate in the study, including completion of all study-related procedures, evaluations and questionnaires, and documents this agreement by signing the Ethics Committee / IRB approved informed consent.

Exclusion criteria

1. Additional surgical intervention for POP repair concurrent to the Gynecare Prolift +M

procedure (e.g. paravaginal repair, sacrocolpopexy, colporrophy in a non-Gynecare Prolift+M treated compartment).
2. Previous repair of pelvic organ prolapse involving insertion of mesh.
3. Previous hysterectomy within 6 months of scheduled surgery.
4. Experimental drug or experimental medical device within 3 months prior to the planned procedure.
5. Active genital, urinary or systemic infection at the time of the surgical procedure. Surgery may be delayed in such subjects until the infection is cleared.
6. Coagulation disorder or on therapeutic anticoagulant therapy at the time of surgery.
7. History of chemotherapy or pelvic radiation therapy.
8. Systemic disease known to affect bladder or bowel function (e.g. Parkinson*s disease, multiple sclerosis, spina bifida, spinal cord injury or trauma).
9. Current evaluation or treatment for chronic pelvic pain (e.g. interstitial cystitis, endometriosis, coccydynia, vulvadynia).
10. Nursing or pregnant or intends future pregnancy.
11. In the investigator*s opinion, any medical condition or psychiatric illness that could potentially be life threatening or affect their ability to complete the study visits according to this protocol.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2008
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	The GYNECARE PROLIFT +M* Pelvic Floor Repair System
Registration:	No

Ethics review

Approved WMO Date:	28-05-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-02-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-06-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL19722.098.07