A Prospective, Multi-Center Study to Assess the AMS Pelvic Floor Repair System Devices for Prolapse Repair

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Long-term evaluation of efficacy and safety of the AMS Pelvic Floor Repair System devices for prolapse repair

Ethical review	Approved WMO
Status	Pending
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32218

Source
ToetsingOnline

Brief title
PROPEL

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
genital prolapse, pelvic organ prolapse

Research involving
Human

Sponsors and support

Primary sponsor: American Medical Systems
Source(s) of monetary or material Support: Industria (American Medical Systems)

Intervention

Keyword: device, Prolapse surgery, quality of live

Outcome measures

Primary outcome

Percent of subjects with an ICS POP-Q Stage of < Stage I at one year post procedure

Secondary outcome

1) Quality of Life (QoL) status * defined as the improvement in subjects* QoL over baseline values for:

* Pelvic Floor Distress Inventory (PFDI) to assess the impact of urinary, prolapse and colorectal distress at 6, 12 and 24 months.

* Pelvic Floor Impact Questionnaire (PFIQ-7) to assess the life impact of pelvic floor disorders at 6, 12 and 24 months post procedure.

* Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire- short form (PISQ-12) to assess the sexual function associated with genital prolapse at 6, 12, and 24 months post procedure.

2) Procedural Time * defined as the time between the first incision to place the specific prolapse device to the last appendage pull through (with or without lateral attachments) and closure of the vaginal incision for the specific prolapse device.

3) Estimated Blood Loss (EBL) * defined as the estimated blood loss associated with each specific AMS PFR System device for prolapse repair during the entire implant procedure.

4) Percent of subjects experiencing major device-related complications, such as

the following:

* Perforation of the internal organs (excluding

the bladder) during the implant procedure

* Graft erosion (away from the vagina) through the wall of bladder, bowel,

rectum or urethra causing clinical complications

* Graft extrusion (into the vagina) resulting in major treatment (surgical

revision or excision)

* Serious infection requiring intravenous (IV)

antibiotics

* Death, related to procedure or device

* Blood loss related to device placement requiring blood transfusion during

AMS PFR device- related portion(s) of the procedure

5) Rate of Graft Extrusion of AMS PFR System devices for prolapse repair *

defined as graft exposure/protrusion through the vaginal wall. Graft extrusion

will be classified by the type of treatment received (i.e., no treatment,

non-invasive treatment (oral and/or topical medication only), minor treatment

(cautery with AgNO3, electrocautery, or trimming), or major treatment (surgical

revision/graft excision). Location of extrusion and timing of diagnosis will

also be collected. Graft extrusion resulting in major treatment will be

reported with major device-related complications.

6) Rate, onset and type of de novo or worsening urinary and/or anal

incontinence

7) Interval POP-Q Staging: POP-Q staging at 6 and 24 months post procedure --

defined by the percent of subjects with an ICS POP-Q Stage of < Stage I at 6

and 24 months post procedure.

8) Pain -- defined as the level of pain or discomfort associated with the pelvic area experienced and measured at baseline and 6 weeks and 3 months post procedure using the Wong-Baker Faces Pain Scale.

9) Subject satisfaction with experience and outcomes of the procedure, as reported on Patient Satisfaction Questionnaires at 6, 12 and 24 months post-procedure.

10) Rate of Surgical Revision* percent of subjects who return to the operating room for adjustment or removal of an AMS PFR System device(s) for prolapse repair.

Study description

Background summary

All the products to be studied within this trial have received market clearance from the United States Food and Drug Administration (FDA). Product improvements and iterations may be introduced into the study upon availability as they are cleared by the FDA with notification sent to study sites as applicable.

Study objective

Long-term evaluation of efficacy and safety of the AMS Pelvic Floor Repair System devices for prolapse repair

Study design

Prospective mult-centre observational study

Study burden and risks

None (no invasive outcome measurements are performed)

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

These include females who:
1) Have been diagnosed with one or more clinically significant anterior, apical or posterior genital prolapse disorder(s) (symptomatic POP-Q stage II or higher) requiring surgical repair
2) Are > 21 years old

Exclusion criteria

1) The Investigator determines the subject is not a candidate for surgical repair of her genital prolapse.
2) Subject has had a prior prolapse implant/procedure (i.e., IVS tunneler, Perigee,

Apogee, graft augmented repair, etc) Note: previous traditional repairs are allowed.
3) Subject has active or latent systemic infection or signs of tissue necrosis.
4) Subject has restricted leg motion (inability to abduct or adduct leg positioning in the lithotomy position) with or without a hip replacement/prosthesis.
5) Subject is currently pregnant or intends to become pregnant during the study period. Note: the risks and benefits of performing the procedure if the subject is planning future pregnancies should be carefully considered.
6) Subject has had radiation therapy to the pelvic area.
7) Subject has pelvic cancer, has had pelvic cancer within the past 12 months or has been on cytostatic medication within the past 12 months.
8) Subject has a known hypersensitivity to the graft material(s).
9) Subject has uncontrolled diabetes.
10) Subject is on any medication which could result in compromised immune response, such as immune modulators.
11) Subject was involved in any other research trial < 30 days of enrollment into this study.
12) Subject has undergone previous pelvic surgery < 6 months prior to enrollment in this study.
13) Subject is unwilling or unable to give valid informed consent.
14) Subject is unwilling or unable to comply with the requirements of the protocol, complete all Quality of Life questionnaires and return for all follow-up visits.
15) Subject is contraindicated based on intended use and warnings in the AMS PFR System devices for prolapse repair Instructions for Use (IFU).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Elevate medical device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22550.018.08