SUperiority of Perineoplasty as concomitant surgical procedure during Pelvic Organ prolapse Repair: a comparative cohort Trial (SUPPORT)

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This study aims to demonstrate superiority of the research intervention (over standard of care) in [1] surgical success and [2] cost-effectiveness and non-inferiority in morbidity

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON51797

Source
ToetsingOnline

Brief title
SUPPORT

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
prolapse

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cost-effectiveness, perineoplasty, recurrence, vaginal prolapse surgery

Outcome measures

Primary outcome

Primary Outcome: Surgical success, which is a composite outcome defined as meeting the 3 following conditions: [1] *much improved* or *improved* in response to the patient global impression of improvement questionnaire, [2] no re-intervention performed in the same compartment within the first 12 months after index surgery, [3] no stage 2 or more POP in the operated compartment
Secondary outcomes: Morbidity: complications and re-interventions due to complications

Secondary outcome

Secondary outcomes: Morbidity: complications and re-interventions due to complications, pain. Effectiveness: disease specific and general quality of life. Anatomical outcomes. Societal costs.

Study description

Background summary

Yearly about 17,000 operations are performed in the Netherlands to repair pelvic organ prolapse (POP), The aim of prolapse surgery is to restore pelvic floor function by correcting the anatomical abnormalities involved in POP as optimally as possible. One of the main problems with pelvic organ surgery is the high rate of recurrent prolapse. One out of every nine women is operated for POP but one out of four surgical procedures is performed in a patient that has been operated before for POP.
In order to restore pelvic floor function, the support of the vagina needs to be reinforced. The vagina is according to deLancey supported at three levels. Level I the upper suspensory ligaments (apical support of the vagina)

Level II pubocervical and rectovaginal fasciae (lateral support of the vagina)
Level III pelvic floor muscles of the levator ani. (support of the vagina to the perineal body)
Loss of level I support leads to prolapse of the uterus or vaginal vault (in case of previous hysterectomy), level II defects lead to recto-, entero- and cystoceles and insufficient level III support leads to a wide vaginal hiatus, which predisposes for (recurrent) pelvic organ prolapse. Worldwide clinical practice has always focused on level I and level II repair, about which there is a large amount of research and solid evidence about which intervention should be performed for which indication. However, there is a paucity of evidence on the added value of surgery to address level III support, which results in significant practice variation. The decision whether or not to perform level III repair depends fully on the individual preference of the surgeon. In addition, perineoplasty has among many gynecologists a bad reputation as in the past the surgical technique involved the puborectal muscles which is associated with a significant risk of de novo dyspareunia. The surgical technique that is proposed in this project involves the bulbocavernosus muscles, which is unlikely to result in dyspareunia. It is known that a wide genital hiatus is related to both a higher risk of level II defect and a higher risk of recurrent prolapse after prolapse surgery. As a result we hypothesize that perineoplasty reduces the size of the genital hiatus and so, reduces the risk of recurrent prolapse. This is suggested by some retrospective studies, and supported by clinical observation. However, well designed prospective studies have never been performed, explaining the lack of agreement about the exact added value of perineoplasty and significant practice variation.

Study objective

This study aims to demonstrate superiority of the research intervention (over standard of care) in [1] surgical success and [2] cost-effectiveness and non-inferiority in morbidity

Study design

Prospective comparative cohort study.

Study burden and risks

The burden is minimal (filling in the questionnaire four times and visiting two extra outpatient clinics). This is also estimated as such by the patient organisation.
The risk is negligible because it concerns evaluation of usual care.

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

Patients >18 years indicated for vaginal POP surgery
Inlcusion criteria:
1. Female patient> 18 years of age
2. Complaints of pelvic organ prolapse
3. Indication for vaginal native tissue prolapse surgery (level I and/or level II repair)
4.Genital hiatus (GH) according to POP-Q staging of >=4 cm and <=7 cm

Exclusion criteria

Exclusion criteria:

1. Unable to understand the Dutch language
2. Pregnancy at baseline or intendancy to become pregnant during the study period
3. Patients with previous surgery for POP (previous mid urethral sling operation for stress urinary incontinence not excluded)
4. Unwilling to participate in the study and/or incapable of giving informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2023
Enrollment:	288
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2023
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	NL82381.018.22