TORBO: Research in Twente on Recurrences after Pelvic Organ Prolapse Surgery

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Objective: This protocol describes a framework that will be used to create different studies. The general primary and secondary objectives of this protocol are stated below:Primary objective: Investigate the effect of surgery on the position and…

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

Summary

ID

NL-OMON50745

Source
ToetsingOnline

Brief title
TORBO

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
pelvic floor dysfunction, prolapse, recurrence

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen
Source(s) of monetary or material Support: ZGT Wetenschapsvoucher en PIHC vocuher 2023

Intervention

Keyword: Pelvic Organ Prolapse, Recurrence, Surgery, Upright MRI

Outcome measures

Primary outcome

In general, the main study endpoints are parameters about the position, shape

and functioning of the pelvic floor and its muscles before and after surgery.

Both absolute parameter values and changes in these parameter between different

time points will be evaluated.

Secondary outcome

Secondary outcome parameters will be described in the dedicated appendices.

Study description

Background summary

Rationale: Pelvic organ prolapse (POP) is characterized by a pelvic floor organ (e.g. bladder, uterus, bowel) protruding (prolapsing) from the opening of the vagina. The main treatment options for POP are conservative treatment with a pessary or surgical correction. In the Netherlands, the prevalence of symptomatic POP in women between 45-85 years is 11.4% and the average number of women who receive surgery based on complaints of POP or urinary/fecal incontinence are as high as 10-20%. Multiple (combinations of) POP are defined, based on the prolapsed organ: anterior, apical and posterior compartment prolapse. Based on the physical complaints, recurrence surgery and the prolapsed compartment(s) the best surgical treatment option is selected. The different options are: anterior/posterior colporrhaphy, sacrospinal fixation (SSF), (modified) Manchester Fothergill (MF), rectopexy, sacrocolpopexy (SCP) and vaginal hysterectomy (VH). Surgical correction has turned out to be highly effective, however the estimated risk of reoperation over a period of 4 years is 30%, while reasons for recurrences are poorly understood. At the University of Twente (UT) we have the unique possibility of visualizing the pelvic floor, and pelvic organ prolapse in upright position.
Hypothesis: Recurrences and continuation of physical complaints might be related to the pre-operative and post-operative (incomplete) assessment of the prolapse (POP-Q) in supine position. Crucial anatomical details, related to

surgical treatment and success are missed or underdiagnosed.

Study objective

Objective: This protocol describes a framework that will be used to create different studies. The general primary and secondary objectives of this protocol are stated below:
Primary objective:
Investigate the effect of surgery on the position and shape of the pelvic organs, the functionality of the pelvic floor muscles and it relation to recurrences and differences in the assessment of prolapse recurrences in supine and upright position.
Secondary objectives:
• Evaluate to what extend pelvic organ prolapse is lifted at 6 weeks after surgery in supine and upright position
• Evaluate the correlation between improvement in physical discomfort/complaints after surgery (based on questionnaires) and the changes in anatomy (based on imaging).
• Evaluate the percentage of recurrences after surgery in upright position (based on imaging) as compared to currently known percentages in supine straining position (based on physical examination)
• How do recurrences develop over time?
• What are the main difference before surgery and after surgery between patients with and without recurrences?
• What is the relation between MRI based anatomical parameters, ultrasound based pelvic floor muscle function, physical examination (POP-Q as is regularly done in clinical practice) and patient*s experiences (questionnaires)?

Study design

This document is a framework from which different studies will be established in different phases (as was done for the EPPA-study ref number: NL74061.091.20). Each study is designed as a prospective (multiple) cohort longitudinal study

Study burden and risks

In the first study (Appendix 1 - Blaasverzakking) we ask patients with surgery for at least a prolapse of the anterior compartment (e.g. bladder) to visit the ZGT hospital and University of Twente for a total of four times (pre-operative; 6 weeks post-operative; 1 year post-operative; 2 years post-operative).
In the second study (Appendix 2-Rectopexy) we ask patients planned for rectopexy surgery to visit the ZGT hospital and University of Twente for a total of three times (pre-operative; 6 weeks and 1 year post-operative).
ZGT visits: During these visits of approximately 30 minutes, patients will undergo physical examination (POP-Q measurement), fill in four questionnaires

(PGI-I, UDI, PISQ and ODS, with a total of 20 questions) and have a transperineal ultrasound examination. POP-Q measurements are standard clinical practice, questionnaires are validated with limited amount of questions and the ultrasound is non-invasive (positioned against the labia).
UT visits: During these visits of approximately 30-60 minutes, patients will undergo a supine and upright MR scan (no ionizing radiation) in the 0.25T scanner. During the MR scanning procedure the patient needs to lie or stand still. In upright position, some people may experience some dizziness because of this. To prevent this, the patient is encouraged to move her toes between the different scans. If dizziness is noticed, the scan will be aborted immediately and the participant is turned back to the horizontal position. The risks associated with MRI are negligible (only very limited amount of dizziness reported in previous pelvic floor related scanning).

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

o Symptomatic POP
o POP-Q stage >=2
o Good knowledge of Dutch language
o Signed informed consent
o Planned for pelvic organ prolapse surgery

Exclusion criteria

o Previous pelvic organ prolapse surgery
o Inability to stand for 20minutes without assistance
o Not eligible for MRI (in response to the MRI safety checklist)
o Abdominal circumference >= 143 cm (jeans size >= 52) or weight >= 200kg
o Combined or previous prolaps/incontinence surgery (e.g. placement of TVT/TVT-O or TOT sling to improve continence).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2022
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL79717.091.21