

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

Published: 23-02-2022

Last updated: 18-07-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Uterine, pelvic and broad ligament disorders
<b>Study type</b>	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 its relation to recurrences and differences in the assessment of prolapse recurrences in supine and upright position.

Secondary objectives:

- Evaluate to what extent 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

### **Public**

Selecteer

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### **Scientific**

Selecteer

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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  $\geq 2$
- 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 20 minutes without assistance
- o Not eligible for MRI (in response to the MRI safety checklist)
- o Abdominal circumference  $\geq 143$  cm (jeans size  $\geq 52$ ) or weight  $\geq 200$  kg
- o Combined or previous prolapse/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