# Biomechanical Assessment of the Vaginal Wall for Pelvic Organ Prolapse

Published: 17-06-2019 Last updated: 12-04-2024

To assess 1) the feasibility of in vivo measurement of biomechanical properties of the vaginal wall with the use of cutometry (Cutometer MPA 580 4mm) and indentometry (Indentometer IDM 800) and 2) the biomechanical properties of the vaginal wall.

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

# Summary

### ID

NL-OMON48346

**Source** ToetsingOnline

**Brief title** IVAP-study

# Condition

Obstetric and gynaecological therapeutic procedures

#### Synonym

cystocele, pelvic organ prolapse, rectocele

### **Research involving** Human

### **Sponsors and support**

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

### Intervention

Keyword: Biomechanical, Elasticity, Tissue, Vagina

### **Outcome measures**

#### **Primary outcome**

Successful measurements of biomechanical properties of the vaginal wall in

patients with vaginal prolapse.

#### Secondary outcome

Not applicable

# **Study description**

#### **Background summary**

In women, the lifetime risk for vaginal prolapse surgery is 11-19%. One fifth of the surgically managed patient have recurrent prolapse surgery. The high recurrence rate might be the result of progressive biomechanical tissue failure. Innovative reconstructive strategies are needed to overcome the high recurrence rate in patients with pelvic organ prolapse. Currently, clinical assessment of these innovations is limited to subjective outcome parameters. Ex vivo research models use biomechanical assessment to study vaginal tissue deformation. Cutometry and indentometry are widely applied non-invasive measure techniques to assess biomechanical properties in soft tissue. Reproducible in vivo measurement of objective functional parameters in the vaginal wall with the use of cutometry and indentometry could improve research on reconstructive strategies for vaginal prolapse.

#### **Study objective**

To assess 1) the feasibility of in vivo measurement of biomechanical properties of the vaginal wall with the use of cutometry (Cutometer MPA 580 4mm) and indentometry (Indentometer IDM 800) and 2) the biomechanical properties of the vaginal wall.

### Study design

An observational pilot study.

#### Study burden and risks

Patients will be counseled before the measurements and informed consent will be obtained. During anesthesia and prior to incision, a non-invasive measurement will be performed. The measurement technique is painless and will cause no harm.

# Contacts

**Public** Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105AZ NL **Scientific** Academisch Medisch Centrum

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

Women undergoing surgical repair for pelvic organ prolapse

# **Exclusion criteria**

Not applicable

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2020
Enrollment:	20
Туре:	Actual

# Medical products/devices used

Generic name:	Cutometer and Indentometer
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO Date:	17-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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# **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** CCMO **ID** NL67396.018.18