The external validation of a prediction model for anatomical cystocele recurrence after primary anterior colporrhaphy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55841

Source
ToetsingOnline

Brief title
PARCC study

Condition

- Other condition
- Genitourinary tract disorders NEC

Synonym
pelvic floor dysfunction, pelvic organ prolapse

Health condition

blaasverzakking

Research involving
Human

Sponsors and support

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

Intervention

Keyword: External validation, Pelvic Organ Prolapse, Prediction model, Recurrence

Outcome measures

Primary outcome

The primary goal of this study is external validation of the prediction model for anatomical recurrence after primary anterior colporrhaphy. The main endpoint of this study is the calculated area under the curve (AUC) of the receiving operating curve (ROC).

Secondary outcome

The secundary goal is the identification of other risk factors besides the ones used in the prediction model for anatomical and subjective recurrence of cystocele after primary anterior colporrhaphy, calculated by univariate and multivariate regression analysis.

Study description

Background summary

Pelvic organ prolapse (POP) is a common condition. The lifetime risk of surgery for POP is 13-19%. Cystocele is the most commonly affected compartment of POP. Anatomical recurrence rates are high after surgery for cystocele (31-59%) and reoperation is performed frequently. A prediction model that preoperatively estimates the risk of anatomical cystocele recurrence after anterior colporrhaphy is developed by Vergeldt et al. This model needs external

validation before it can be used in daily urogynaecological practice.

Study objective

The primary objective of this research is external validation of the prediction model that preoperatively estimates the risk of anatomical cystocele recurrence after primary anterior colporrhaphy. The secondary objectives are to identify risk factors for anatomical and subjective cystocele recurrence in women treated for cystocele one year after primary colporrhaphy. Risk factors to be investigated in this study are:
- age at time of surgery
- BMI
- parity and number of vaginal deliveries
- having had an assisted delivery
- preoperative cystocele POPQ stage 3 of 4
- positive family history for POP (mother or sister of the patient with POP)
- number of compartments involved
- simultaneous POP surgery in another compartment at the time of primary anterior colporrhaphy
- levator ani muscle defect prior to surgery (on 3D ultrasound)
- levator hiatal area prior to surgery (on 3D ultrasound)

Study design

The study will be an observational prospective cohort study, with prospective follow-up of women treated for cystocele by a primary anterior colporrhaphy in the participating hospitals.

Study burden and risks

The subjects will not directly benefit from participating in this study. The results of the study and the validation of the prediction model however will help to identify patients with a high or low risk of recurrence of POP in the future. The ultimate goal is to develop a personalised decision aid for patients who will be treated for POP.
The chance on any adverse event due to participation in the study is close to zero. The only possible disadvantages of participating in this study are the possible discomfort of the ultrasound and the gynaecological exam and filling in the questionnaires and the time this requires.

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

All women who are planned for undergoing a primary anterior colporrhaphy because of a cystocele (with a POP-Q stage of 2 and higher) in the participating hospitals who are willing to participate in this study and give informed consent. Women need to be able to complete the questionnaires. A combination of a primary anterior colporrhaphy with other POP or incontinence surgery is permitted.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- < 18 years of age
- Not capable of understanding the Dutch language or other reasons (judged by the clinician) that make informed consent impossible.
- POP or incontinence surgery prior to index surgery
- The use of mesh or implants during surgery (vaginal or abdominal mesh for POP

surgery, tape for incontinence surgery)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2017
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-07-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-01-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	28-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25627
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60381.068.16
OMON	NL-OMON25627