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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25627

Source
NTR

Brief title
PARCC study

Health condition

Pelvic Organ Prolapse
Recurrence
Prediction model
External validation

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: Self-financing research

Intervention

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

Study design

Patients will be analyzed preoperatively and one year postoperatively.

Intervention

Preoperatively, patients will have three dimensional (3D) translabial ultrasound to detect levator defects and to measure the levator hiatus. Also, patients will complete a questionnaire about obstetrical history, family history for POP and the presence and severity of urogynaecological complaints.

Patients will undergo surgery according to the daily practice.

One year after surgery, patients will be seen for a follow-up visit in which prolapse quantification will be performed and the same questionnaire will be completed.

Contacts

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Eligibility criteria

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

- < 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 non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2017
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55841
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6292
NTR-old	NTR6466
CCMO	NL60381.068.16

Register	ID
OMON	NL-OMON55841

Study results