Prevalence of overactive bladder (OAB) in patients with pelvic organ prolapse (POP) and predictors of symptoms of OAB after surgical correction of POP.

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The primary aim of this research project is to investigate the prevalence and bother of OAB before and after POP repair surgery and to determine changes in bladder function after surgery. Secondary aim is to identify predictors of persistence,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON35445

Source
ToetsingOnline

Brief title
OAB&POP: overactive bladder in women with prolapse before and after surgery

Condition

- Urinary tract signs and symptoms
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
in women with genital prolapse, Overactive bladder symptoms in women with pelvic organ prolapse - Frequent and strong desire to void, with or without urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Astellas Pharma,Astellas Pharma (farmaceutische industrie) en Continentie Stichting Nederland (collectebusfonds),Continentie Stichting Nederland

Intervention

Keyword: Overactive bladder, Pelvic organ prolapse, Surgical treatment, Urodynamics

Outcome measures

Primary outcome

Main study parameters are the presence of bothersome OAB as measured by bladder diary and validated disease specific questionnaires (UDI, IIQ, ICIQ-FLUTS, OABSS) and the outcomes of urodynamic studies (presence of detrusor overactivity (DO), bladder outflow obstruction (BOO)).

Secondary outcome

Secondary parameters are the outcomes of measurement of POP-Q, ultrasound assesment of bladder wall thickness (BWT) and configuration of urethra and bladder neck, analysis of urinary biomarkers, and the findings of cystoscopy (presence of trabeculation).

Study description

Background summary

Clinically the relation of overactive bladder (OAB) and pelvic organ prolapse (POP) is of great significance. The prevalence of POP stage 2 or more varies from 37% to 50%. A woman*s life-time risk of requiring surgery for POP and/or urinary incontinence is approximately 11%. Symptoms of OAB are present in approximately 50% of patients with POP. For many women the accompanying symptoms of OAB are an important reason for seeking help for their POP. All treatments for POP (surgery, pessaries) show an improvement of OAB complaints.

However, it is unclear what predicts if the OAB symptoms disappear or not after operation. Persisting or de novo OAB symptoms are strongly correlated with dissatisfaction with the final results of an operation for POP.
With better knowledge of prevalence of OAB in patients with POP and predictive factors for the presence of OAB symptoms after surgery, clinicians can better counsel their patients and possibly offer alternative treatment for OAB such as anticholinergics before embarking on surgical treatment.

Study objective

The primary aim of this research project is to investigate the prevalence and bother of OAB before and after POP repair surgery and to determine changes in bladder function after surgery.
Secondary aim is to identify predictors of persistence, disappearance or de novo symptoms of OAB after POP repair surgery.

Study design

The study is a single centre prospective observational study performed in the departments Urology and Gynaecology of the Radboud University Nijmegen Medical Centre, The Netherlands.

Study burden and risks

Participation in this study is associated with negligible risks and limited additional burden for patients. Pre- and postoperative evaluations with completion of questionnaires and bladder diary, pelvic examination, as well as preoperative urodynamics are standard elements of medical care. The additional ultrasound, urine sampling and cystoscopy do not require additional clinic visits, as these can be performed during the planned outpatient clinic visits, urodynamic investigation and surgery respectively. One extra moment of follow-up at six months will be planned, which requires one extra clinic visit. The postoperative urodynamic investigation also requires one extra clinic visit.

Both urodynamics and cystoscopy do usually not generate major morbidity or serious complications. Generally, these investigations are associated with discomfort during the procedure and transient discomfort, dysuria, and a low risk of urinary tract infection following the procedure. The cystoscopy is performed under anesthesia before start of the actual surgery and will therefore not generate any extra discomfort. Due to standard prophylactic use of antibiotics during surgery no extra risk of urinary tract infection exists.
Bladder wall thickness measurements and assessment of configuration of urethra and bladder neck using transvaginal ultrasound are non-invasive and minimally disturbing for the patient.
Urine samples are collected during urodynamic investigation. The urine which is

normally discarded will be collected and stored. This is not inconvenient for the patient.

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

- Female patients, age 18 or greater, with a pelvic organ prolapse POP-Q stage II to IV .
- Patient will undergo prolapse repair surgery.
- Patient understands the Dutch written and spoken language.

Exclusion criteria

- Patients who currently use anticholinergic medication.
- Patients with neurological causes of OAB.
- Patients who are pregnant or wish to become pregnant.
- Patients with a history of cancer in the pelvic region, treated with radiotherapy or surgery.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2012
Application type:	First submission
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	NL38563.091.11