Removal of indwelling urinary catheter after vaginal prolapse surgery; removal on first night versus first morning after surgery.

Published: 13-12-2018
Last updated: 10-04-2024

Primary objective: Does removal of an IUC late at night on the day of vaginal prolapse surgery lead to a decrease in clinical UTIs in the first six weeks after surgery compared to removal on the morning of the first day after surgery?Secondary…

Ethical review	Not approved
Status	Will not start
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON46473

Source
ToetsingOnline

Brief title
PUC-study: removing Postoperative Urinary Catheter after prolpase surgery.

Condition

- Urinary tract signs and symptoms
- Obstetric and gynaecological therapeutic procedures

Synonym
urine retention; urine tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: ziekenhuis betaald de kosten

Intervention

Keyword: catheter, prolapse, removal, surgery

Outcome measures

Primary outcome

Amount of clinically suspected UTIs within 6 weeks after surgery.

Secondary outcome

- Occurrence of a PVR >150cc after removal of the IUC in two consecutive

measurements after two different attempts for micturition.

- Occurrence of asymptomatic bacteriuria developing into a clinically suspected

UTI within 6 weeks after surgery.

- Patient satisfaction at discharge from the hospital.

- Total duration of admittance to the hospital

- Total duration of catheterisation

Study description

Background summary

After vaginal prolapse surgery an indwelling urinary catheter (IUC) is placed. Often it is removed on the first postoperative day. After removal of the IUC 10-40% of patients is unable to fully empty the bladder during micturition. Among contributing factors are fear and preoccupation with micturition. In these cases temporary subsequent catheterisation is needed. Research shows that with longer duration of initial catheterisation chances of developing an urinary tract infection (UTI) increase, while chances of incomplete bladder emptying decrease. To reduce the influence of fear and preoccupation with micturition it can be considered removing the IUC late at night instead of

early in the morning.

Study objective

Primary objective: Does removal of an IUC late at night on the day of vaginal prolapse surgery lead to a decrease in clinical UTIs in the first six weeks after surgery compared to removal on the morning of the first day after surgery?
Secondary objective: Is the chance on early dysfunctional voiding comparable when an IUC is removed late at night on the day of vaginal prolapse surgery compared to removal on the morning of the first day after surgery?

Study design

Multicentre randomised controlled trial with nested cohort study.

Intervention

In the study group IUC is removed at night on the day of the surgery. In the control group the IUC is removed on the morning of the day after surgery.

Study burden and risks

N/A

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

Patients aged 18 years or older undergoing surgery for vaginal prolapse.

Exclusion criteria

1. Existing neurological disorder which is likely to influence bladder function (e.g. dementia, MS, spinal disc herniation)
2. Existing anxiety disorder
3. Insufficient comprehension of the Dutch language
4. Concurrent surgery for incontinence (e.g. midurethral sling, burch colposuspension)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL
Recruitment status: Will not start

Enrollment:	300
Type:	Anticipated

Ethics review

Not approved

Date:	13-12-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL64233.099.18