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Comparison of the postoperative rate of complications and infections in indwelling and suprapubic urinary catheters

Submission date
27/11/2008

Recruitment status
No longer recruiting

Registration date
16/01/2009

Overall study status
Completed

Last Edited
16/03/2011

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ute Kringel

Contact details
Department of Obstetrics and Gynaecology
University of Rostock
Suedring 81
Rostock
Germany
18059
+49 381 4401 4700
ute.kringel@uni-rostock.de

Additional identifiers

Protocol serial number
1

Study information

Scientific Title

Comparison of the postoperative rate of complications and infections in indwelling urinary catheters and suprapubic catheters after anterior colporrhaphia: a three-arm prospective randomised trial

Study objectives
Suprapubic (Arm C) and indwelling urinary catheters (IUCs) for 96 hours (Arm B) are preferred in Europe after operations, including anterior colporrhaphia.

Hypothesis 1: If there is no difference in infection or complication rate between IUCs for 96 hours (Arm B) and IUCs for 24 hours (Arm A), the latter will be considered sufficient.
Hypothesis 2: If IUCs for 24 hours (Arm A) have no higher rate of infections and complications compared to suprapubic catheter for 96 hours (Arm C), the former could be considered sufficient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty, Institute of Forensic Medicine, University of Rostock, approved on 02/02/2007 (ref: HV 03/2007)

Primary study design
Interventional

Study design
Randomised controlled single-centre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urinary tract infection after operation

Interventions
Method of randomisation: permutated block randomisation with variable block length
Duration of recruitment: 12 months

Arm A: IUCs for 24 hours
Arm B: IUCs for 96 hours
Arm C: suprapubic catheter for 96 hours

In Arm A and B the indwelling catheter was installed under sterile conditions preoperatively by a scrub nurse. In Arm C the catheter was inserted under sterile conditions directly after theatre by the performing surgeon.

Total duration of follow-up: until discharge (mean value: 6.85 days +/- 1.45).

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Rate of urinary tract infection at 4 days after operation.

Key secondary outcome(s)
Complications, assessed on the day of discharge (mean value: 6.85 days +/- 1.45).

Completion date
29/02/2008

Eligibility

Key inclusion criteria
1. Female patients
2. 45-85 year old
3. Patients with a planned anterior colporrhaphia
4. Patient's consent
5. Urine analysis and urine culture immediately before and 4 days after the operation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Symptomatic urinary tract infection preoperatively
2. Epidural anaesthesia

Date of first enrolment
01/03/2007

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
Germany

Study participating centre

Department of Obstetrics and Gynaecology
Rostock
Germany
18059

Sponsor information

Organisation
University of Rostock (Germany)

ROR
https://ror.org/03zdwsf69

Funder(s)

Funder type
University/education

Funder Name
University of Rostock (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No