

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	<input type="checkbox"/> Prospectively registered
Registration date 16/01/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/03/2011	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Randomised controlled single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Urinary tract infection after operation

Interventions

Method of randomisation: permuted 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 measure

Rate of urinary tract infection at 4 days after operation.

Secondary outcome measures

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

Overall study start date

01/03/2007

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

Age group

Adult

Sex

Female

Target number of participants

300

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)

Sponsor details

Medical Faculty

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Sponsor type

University/education

Website

<http://www.kliniksued-rostock.de/klinikum/>

ROR

<https://ror.org/03zdwsf69>

Funder(s)

Funder type

University/education

Funder Name

University of Rostock (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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