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

Submission date	Recruitment status	[_] Prospectively registered
27/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2011	Urological and Genital Diseases	

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: 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 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
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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