

Impact of rectal washout on bacterial contamination caused by transrectal access for natural-orifice transluminal endoscopic surgery (NOTES)

Submission date 05/10/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/11/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Impact of rectal washout on bacterial contamination caused by transrectal access for natural-orifice transluminal endoscopic surgery (NOTES): a randomized controlled trial

Acronym

NOBACT II

Study objectives

The null-hypothesis states that the probability of bacterial contamination caused by transrectal access measured by a swab of the circular staplers center rod is the same for experimental intervention and control intervention. The alternative hypothesis states that the experimental interventions and the control intervention perform differently in terms of primary efficacy endpoint.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Heidelberg approved on 25/05/2011, (ref: S-396/2010)

Study design

Prospective randomized controlled patient-blinded surgical trial with three parallel study groups

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients undergoing sigmoid resection or left hemicolectomy

Interventions

Experimental intervention:

1. Rectal washout with 5% povidon iodine using an applicator
2. Rectal washout with sodium chloride (NaCl) using an applicator

Control intervention:

Rectal washout with NaCl using an irrigation syringe

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

5% povidon iodine

Primary outcome(s)

Bacterial contamination at the circular staplers center rod following experimental intervention (rectal washout with 5% povidone iodine using an applicator) and control intervention

Key secondary outcome(s)

1. Bacterial contamination at the circular staplers center rod following experimental intervention (rectal washout with NaCl using an applicator)
2. Bacterial count and routine cultures at rectal mucosa, center rod, small pelvis
3. Exploratory analyses

Completion date

01/12/2012

Eligibility

Key inclusion criteria

1. Given indication for sigmoid resection or left hemicolectomy with primary anastomosis in the proximal rectum
2. Age > 18 years
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. American Society of Anesthesiology patient (ASA) classification IV and V
2. Emergency operation (obstruction, bleeding, peritonitis)
3. Hand-sutured anastomosis
4. Ileus, colitis, pelvic infection
5. Reoperation
6. Anastomosis < 6cm from the anus
7. Ongoing antibiotic therapy
8. Iodine allergy
9. Hyperthyreosis

Date of first enrolment

01/12/2011

Date of final enrolment

01/12/2012

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Allgemein-, Viszeral- und Transplantationschirurgie

Heidelberg

Germany

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Sponsor information

Organisation

University of Heidelberg (Germany)

ROR

<https://ror.org/038t36y30>

Funder(s)

Funder type

University/education

Funder Name

University of Heidelberg (Germany)

Alternative Name(s)

Ruprecht-Karls-Universität Heidelberg, University of Heidelberg

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration