Prevention of wound infections after colorectal surgery using antibiotics prior to surgery

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20443

Source
Nationaal Trial Register

Brief title
PreCaution

Health condition

Surgical site infection; Post procedural wound infection; Postoperative wound infection; Colorectal surgery

Dutch: Postoperatieve wondinfectie; Colorectale operatie

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMw - The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

The cumulative incidence of deep surgical site infections and/or mortality within 30 days after elective colorectal surgery

Secondary outcome

1. Deep surgical site infections

2. 30-day mortality

3. Superficial surgical site infections

4. Anastomotic leakage

5. Relaparotomy

6. Bacteremia

7. Infections with highly resistant Enterobacteriaceae (HRE) or Clostridium difficile

8. Presence of HRE in intestinal flora

9. In-hospital use of antibiotics

10. 6-month mortality

11. Postoperative length of hospital stay

12. Postoperative length of ICU stay

13. Quality of life

14. In-hospital costs

Study description

Background summary

Background

Colorectal surgery is frequently complicated by surgical site infections (SSIs). The main consequences of SSIs are prolonged hospitalization, increased risk of surgical reintervention and increased mortality. Perioperative intravenous antibiotic prophylaxis is a common strategy to reduce the risk of SSIs. Preoperative oral antibiotic prophylaxis (Pre-OP) has been suggested as an additional prophylaxis to further reduce the risk of infection. The main

objective of the PreCaution trial is to evaluate the effectiveness of Pre-OP in addition to intravenous perioperative antibiotic prophylaxis in reducing the incidence of deep SSIs and/or mortality after elective colorectal surgery.

Methods / Design

The PreCaution trial is designed as a multicenter, double-blind, randomized, placebo-controlled clinical trial that will be carried out in Dutch hospitals. Adult patients who will undergo elective colorectal surgery and who do not meet any of the exclusion criteria are eligible to participate in the trial. A total number of 966 patients will be randomized to receive study medication, which will either be Pre-OP, consisting of tobramycin and colistin sulphate, or a placebo. The study medication will be administered four times daily during the last 3 days prior to surgery. Perioperative intravenous antibiotic prophylaxis will be administered to all patients in accordance with the national infection control guidelines. The primary endpoint of the study is the cumulative incidence of deep SSI and/or mortality within 30 days after surgery. Secondary endpoints include both infectious and non-infectious complications of colorectal surgery. The endpoints will be evaluated on postoperative day 30 and after completion of the 6-month follow-up period.

To conclude, the PreCaution trial will investigate whether Pre-OP in addition to intravenous perioperative antibiotic prophylaxis will reduce the risk of SSIs and mortality after elective colorectal surgery. The results of the trial will be of great value to enable evidence-based recommendations regarding the effect of Pre-OP on patient outcomes and healthcare costs.

Study objective

It is hypothesized that a preoperative oral antibiotic prophylaxis, that is administered in addition to perioperative intravenous prophylaxis, will lead to a reduction in postoperative would infections after colorectal surgery

Study design

The endpoints will be evaluated on postoperative day 30 and after completion of the 6-month follow-up period.

Intervention

Intervention

The intervention is a preoperative oral antibiotic prophylaxis (Pre-OP), which is a solution of colistin sulphate and tobramycin. Pre-OP is administered 4 times daily (5 mL per dose) during the last 3 days prior to surgery.

Control group

The control group receives a placebo without the active antimicrobial ingredients but with a similar taste and color.

All patients receive perioperative intravenous antibiotic prophylaxis in accordance with the national infection control guidelines.

Contacts

Public
Amphia Hospital
PObox 90158
J.A.J.W. Kluytmans
Breda 4800 RK
The Netherlands
+31 (0)76 5953015
Scientific
Amphia Hospital
PObox 90158
J.A.J.W. Kluytmans
Breda 4800 RK
The Netherlands
+31 (0)76 5953015

Eligibility criteria

Inclusion criteria

• Patients aged 18 years or older

• Patients undergoing elective colorectal surgery

• Patients may not meet any of the exclusion criteria

Exclusion criteria

• Patients aged <18 years

• Legally incapacitated patients or patients who refuse to sign informed consent

• Patients who are unable to take oral medication

• Patients who have undergoing abdominal surgery 30 days prior to randomization

• Patients who have a documented allergy to any of the medications or agents that are used (i.e. colistin sulphate, tobramycin or other aminoglycosides)

• Patients diagnosed with myastenia gravis

• Pregnant women and nursing mothers

• Patients undergoing colorectal surgery in an emergency setting

• Patients with a stoma

• Patients who already participated in the PreCaution trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	19-04-2017
Enrollment:	966
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47368
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5932
NTR-old	NTR6113
CCMO	NL56697.041.16
OMON	NL-OMON47368

Study results

Summary results
N.A.