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

Gepubliceerd: 11-10-2016 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20443

Bron
Nationaal Trial Register

Verkorte titel
PreCaution

Aandoening

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

Dutch: Postoperatieve wondinfectie; Colorectale operatie

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: ZonMw - The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients aged 18 years or older

• Patients undergoing elective colorectal surgery

• Patients may not meet any of the exclusion criteria

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	19-04-2017
Aantal proefpersonen:	966
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47368
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N.A.