Effect of an Enhanced PerOperative Care and Health Program

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25119

Source
Nationaal Trial Register

Brief title
EPOCH

Health condition

Surgical site infections (SSI's), randomised study, randomized controlled trial,

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
Source(s) of monetary or material Support: ZonMW
Innovatie fonds zorgverzekeraars
Johnson & Johnson Ethicon

Intervention

Outcome measures

Primary outcome

Incidence rate of SSI evaluated from the Dutch National Surgical Complication Registry (LHCR). Parallel assessment of incidence rate of SSI by the CDC definition through medical chart reviews.

Secondary outcome

- SSI rate evaluated at 30 days and 3 months follow-up by the CDC definition through medical chart review.

- Readmission rate at 30 days follow up through LHCR registration

- WHO disability assessment schedule 2.0 by self-administration through online/paper-form questionnaires at postop day 30, 60 and 90.

- (In)direct medical and non-medical costs, quality adjusted life years (QALY) (Methods described under CEA and BIA. See below)

- Anastomotic leakage rate at 30 days follow up through LHCR registration and medical chart review.

- Incisional hernia rate by medical chart review (diagnosed by either physical examination and/or ultrasonography or CT) one year after surgery.

Study description

Background summary

In this randomized controlled multicenter trial we evaluate, in adults undergoing elective abdominal surgery, whether an enhanced perioperative care and health protection program, reduces postoperative surgical site infections compared to usual care alone.

Study objective

To evaluate the effect of an enhanced perioperative care program added on to usual care. It is hypothesized that the enhanced perioperative care and health protection (EPOCH) program added on to usual care reduces postoperative surgical site infections compared to usual care alone

Study design

Follow-up at discharge, 1,2, & 3 months after surgery.

Intervention

The EPOCH bundle

An evidence-based, enhanced perioperative care program that can be applied without

introduction of new material in the OR, added on top of usual care, comprising of: 1. Normothermia, 2. Supplemental oxygen, 3. Normovolemia, 4. Normoglycemia and 5. Surgical site handling.

The control group will receive usual care standard oxygenation (30% FiO2), standard hemodynamic therapy based on fluid balance and third space losses, no active preoperative and postoperative warming, no active control of hyperglycemia, and conventional surgical site handling. In the Netherlands the POWI (PostOperative Wound Infection) bundle is usual care and consists of hygiene discipline (focusing on door movements), timing of antibiotic prophylaxis, normothermia, and no preoperative hair removal.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients ¡Ý 18 years

- Elective open abdominal surgery and laparoscopic colorectal surgery

Exclusion criteria

- Emergency surgery

- Reoperation for complications from recent surgery (within 3 months)

- The inability of reading/understanding and filling in the questionnaires

- Participation in another study with interference of study outcomes

- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	3000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5572
NTR-old	NTR5694
Other	METC AMC : METC 2015_121 EPOCH trial

Study results