The Effect of an Enhanced PerOperative Care and Health Protection Programme on Surgical Site Infections (SSI) after elective abdominal surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50566

Source
ToetsingOnline

Brief title
EPOCH trial

Condition

- Bacterial infectious disorders

Synonym
Surgical site infection, Surgical wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Innovatie fonds zorg verzekeraars,Johnson & Johnson,ZonMW;Innovatie fonds zorgverzekeraars;Johnson & Johnson

Intervention

Keyword: Anesthesiology, Perioperartive care, Surgery, Surgical Site infection

Outcome measures

Primary outcome

Incidence rate of SSI at 30 days follow-up, evaluated from the Dutch National Surgical Complication Registry (LHCR), a complication registry that has been implemented for over fifteen years now in Dutch Hospitals.

Secondary outcome

Secondary endpoints: SSI rate evaluated at 3 months follow-up, WHO disability assessment schedule 2.0, (in)direct medical and non-medical costs, quality adjusted life years (QALY) , anastomotic leakage rate, incisional hernia rate, Serious adverse events (SAE) and mortality. Parallel assessment of incidence rate of SSI, by the CDC definition, by medical chart reviews to correct possible registration effect.

Additional secondary outcomes for participants in the AMC: Local tissue oxygenation from admission to the surgical unit until discharge from recovery back to the ward, immunologic effects defined by neutrophil intracellular ROS generation, phagocytosis assays, plasma cytokine concentrations, HLA-DRA mRNA expression, malondialdehyde concentration, blood gas parameters, and ex vivo

whole blood stimulation.

Study description

Background summary

Surgical site infections (SSI) are common after surgery and a major cause of morbidity and mortality, prolonged hospital stay and healthcare costs. SSI often require long and extremely painful wound care and cause a lot of unnecessary pain, fear disability and even death. As with many iatrogenic problems, they disrupt the expectation that health care will be reparative, recuperative or healing and instead involve the patient in suffering an additional burden of pain and impairment: it interrupts the expected progress towards health recovery[1]. Patients report a sense of violation or betrayal having contracted an infection while in the hospital[2] as well as a loss in confidence in health service and a dread of going back[3]. In the Netherlands, of all operated patients 3.9% suffer from an SSI. In gastrointestinal surgery up to 9.3% of all patients encounter a SSI[4]. SSI account for 33% of all healthcare-associated infections (HAIs)[5].
SSIs are not always avoidable but approximately 55% of SSI are deemed preventable with evidence based strategies[6]. However it has become apparent that improvement of individual measures alone is unlikely to result in a clinically relevant effective SSI reduction[7-9]. In contrast, efforts that have used systematic approaches, or bundles, have been successful to varying degrees[10-12]. The care-bundle concept was developed by the Institute for Healthcare Improvement in 2001[79]. Two commonly used and successful application of this approach are the care bundles developed to reduce central venous catheter-line infection and to reduce ventilator associated pneumonia [79]. The Surviving Sepsis Campaign has used the care-bundle concept to improve dramatically the outcomes of patients presenting with sepsis[80]. The Dutch guideline dictates use of the POWI (PostOperative Wound Infection) bundle which includes hygiene discipline (focusing on door movements), timing of antibiotic prophylaxis, normothermia, and no preoperative hair removal[13].
1. There is scarce evidence of this bundle*s effect. A national reduction in SSI has not been demonstrated since implementation[14].
2. In this current bundle only maintaining normothermia (1 out of the 4 POWI bundle measures) has published evidence of being effective in reducing SSI in recent systematic reviews[15-18]. All other 3 measures in the bundle (limited door movements, timing of antibiotic prophylaxis and no preoperative hair removal) are not significantly associated with a reduction in SSI[19-21].
Current evidence suggests that perioperative care can be optimized beyond this bundle. Other risk factors for the development of SSI, that can be targets of intervention, have shown to be of greater importance than 3 of the 4 POWI bundle components. However, budgets are tight and new investments are not

always feasible. We need a set that includes readily available interventions targeted to modifiable risk factors that have a proven effect on SSI.
In this study design, in collaboration with (a) international experts and (b) the WHO, and (c) through consensus with participating centers, we formulated an enhanced perioperative care program (EPOCH) comprising evidence based interventions readily applicable without introduction of new material to reduce SSI, to be added on top of usual care.

Study objective

Our primary objective is to evaluate the effect of an enhanced perioperative care program added on to usual care on the incidence of SSI. Secondary objectives are to evaluate SSI rate at 3 months follow-up, assessment of health and disability with the WHO disability assessment schedule 2.0 and direct and indirect medical and non-medical costs and readmission rates.

As an additional objective we will try to assess the attributive effect on our primary endpoint of the separate components of the current POWI bundle and promising innovative interventions, applied in some practices, outside the bundle under investigation . This will help us to separate benefit from ballast within the current perioperative practice. Ultimately this will contribute to a concise bundle of interventions comprising the effective interventions of current practice and our innovative bundle when proven effective.

Study design

Pragmatic, randomized controlled parallel-group multicenter superiority trial that compares an enhanced (optimized) perioperative care and health protection program combining evidence-based methods to usual care. Randomization will be performed daily per hospital to prevent contamination between groups. To safeguard adherence and persistence tot the study protocol weekly reminders will be sent to anesthesiologists and surgeons, random periodic controls visits to the operating theaters will be made throughout the study duration and a self-score checklist about the interventions after every operation have to be filled out by both surgeon and the anesthesiologist

Intervention

An evidence-based, enhanced perioperative care program that can be applied without introduction of new material in the OR, added to usual care, comprising:
1. Normothermia
- Active perioperative warming
2. Supplemental oxygen (hyperoxygenation)
- FiO2 80%
3. Normovolemia
- Goal directed therapy

4. Normoglycemia
- Blood glucose <10mmoll-1
5. Surgical site handling.
- Alchol based antiseptic
- Dilute PVI/CHX wound irrigation prior to closure

Study burden and risks

For participants of the additional measurements in the AMC: The aminolevulinic acid patch may lead to temporary local side effects at the site of the patch, including irritation, burning sensation, and erythema.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients undergoing elective abdominal surgery resulting in an incision larger than 5 cm

Exclusion criteria

Emergency surgery, reoperations because of complicated surgery within 90 days and two staged surgical procedures

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	1433
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	25-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL52796.018.15