Chlorhexidine-alcohol versus iodine-alcohol for surgical-site antisepsis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25242

Source
Nationaal Trial Register

Brief title
SKINFECT

Health condition

Surgical-site infection, postoperatieve wondinfectie, POWI, SSI

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: fund=initiatior

Intervention

Outcome measures

Primary outcome

Primary endpoint is the occurrence of SSI within 30 days following surgery or within one year following orthopaedic procedures.

Secondary outcome

Secondary endpoints are variations in SSI between indicator operations, wound classification and wound type.

Study description

Background summary

Rationale: Surgical-site infection (SSI) increases morbidity, mortality, length of hospital stay and costs. Optimization of preoperative skin antisepsis may decrease postoperative infections. In the Netherlands, chlorhexidine-alcohol and iodine-alcohol based skin antiseptics are currently used at random in general surgery mostly depending on local or personal preferences.
Objective: To investigate whether either chlorhexidine-alcohol or iodine-alcohol based skin antiseptics is more protective against surgical site infections.

Study design: A prospective pragmatic cluster randomised cross-over trial
Study population: Patients > 18 years of age undergoing general-surgical and/or orthopaedic indicator operations.
Intervention (if applicable): Participating hospitals are randomly assigned to an alternating schedule of either chlorhexidine-alcohol (A) or iodine-alcohol (B) for preoperative skin antisepsis for a time period of three months. After each period of three months for a total study period of one year, hospitals will cross over, resulting in intervention schedules of either ABAB or BABA.

Main study parameters/endpoints: Primary endpoint: Wound infection within 30 days after surgery, or 1 year after surgery with a non-humane implant.
Secondary endpoints: (1) Type of wound infection, (2) Opened wounds (3) microbiologic causes of infection, (4) adverse events
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Preoperative evaluation will include a routine medical history, taking psychical examination, and hematologic and blood chemical laboratory tests.

According to the hospitals assigned cluster, the participant will be subject to painting of the skin with either chlorhexidine-alcohol or iodine-alcohol immediately prior to surgery. Both investigational products have been used for decades for surgical site antisepsis and are considered safe. Minimal side effects have been reported. Participants will undergo routine surgical care and after care. The surgical site will be assessed during hospitalization, on discharge, at the time of follow-up evaluation, and whenever SSI occurs. If SSI is suspected or diagnosed, clinically relevant microbiologic samples will
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be cultured. At 30 days follow-up (or 1 year follow up in case of surgery with non-human

implants), SSI data, collected by PREZIES network, will be analysed.

Study objective

To investigate whether either chlorhexidine-alcohol or iodine-alcohol based skin antiseptics is more protective against surgical site infections.

Study design

Surgical-site infection data will be recorded postoperatively and sent to the PREZIES network. The rate of surgical-site infection will be evaluated 30 days after patient accrual has stopped. Furthermore, all cases with implants will be evaluated for surgical-site infections one year from the end of the study.

Intervention

Participating hospitals are randomly assigned to either chlorhexidine-alcohol (0.5% chlorhexidine in alcohol 70%) or iodine-alcohol (1% iodine in alcohol 70%) for preoperative skin antisepsis for a time period of three months. After the first period of three months, centers will switch to using the other agent for preoperative antisepsis. Centers will switch each 3 months for 3 times and will actively be contacted two weeks before a switch will take place.
Patients will undergo routine surgical care and after care. The surgical site will be assessed regularly during hospitalization, on discharge, at the time of follow-up evaluation, and whenever SSI occurs.

Contacts

Public
Charehbili
Leiden
The Netherlands
Scientific
Charehbili
Leiden
The Netherlands

Eligibility criteria

Inclusion criteria

All patients undergoing general surgical and/or orthopedic indicator operations that are reported to Prezies-network.

Exclusion criteria

- Inability to complete 30 days follow-up;

- < 18 years of age;

- Evidence of infection at or adjacent to the operative site;

- History of allergy for chlorhexidine, alcohol or idiophors.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	4000
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

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	NL3835
NTR-old	NTR4004
Other	METC nummer : 12-206
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results