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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25242

Bron
Nationaal Trial Register

Verkorte titel
SKINFECT

Aandoening

Surgical-site infection, postoperatieve wondinfectie, POWI, SSI

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: fund=initiatior

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

following orthopaedic procedures.

Toelichting onderzoek

Achtergrond van het onderzoek

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
SKINFECT Trial, version 2.1 24-10-2012
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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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Charehbili
Leiden
The Netherlands

Wetenschappelijk

Charehbili
Leiden
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	4000
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3835
NTR-old	NTR4004
Ander register	METC nummer : 12-206
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten