Efficacy of medicinal honey to reduce catheter insertion site colonization of intensive care patients

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We aim to study the efficacy of honey to prevent skin colonization with microflora at central venous catheter insertion sites.

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

Summary

ID

NL-OMON31062

Source
ToetsingOnline

Brief title
Honey to reduce catheter insertion site colonization

Condition

- Bacterial infectious disorders

Synonym
catheter-related infections, line sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,SENTER Economische Zaken

Intervention

Keyword: antibacterial, catheter insertion site, honey, IC patient

Outcome measures

Primary outcome

The primary study parameter is frequency of positive skin swabs cultures at the

last sampling point before removal of the catheter, or before the patient

leaves the intensive care department.

Secondary outcome

not applicable

Study description

Background summary

Catheter-related bloodstream infections form a serious problem in critically ill patients. These infections may originate either from the skin microflora (extraluminal source), or from contaminated hubs or fluids (intraluminal source). Although the skin is intensively disinfected prior to catheter insertion and a sterile dressing is applied, micro-organisms residing in e.g., hair follicles re-colonize the skin under the dressing. Application of medical grade honey might result in prolonged disinfection of skin around catheter-insertion sites.
Medical grade honey has antimicrobial activity through its high sugar content, the presence of glucose-oxidase producing hydrogen peroxide, low pH and additional yet unidentified bactericidal compounds. Honey has been tested for its clinical applicability with promising results.
At the department of Medical Microbiology at the AMC, the antimicrobial activity of medical grade honey was determined. In a pilot-study with healthy volunteers, we showed that medical grade honey strongly reduces colonization of forearm skin (unpublished data). We aim to assess the efficacy of medical grade honey to reduce central venous catheter insertion site colonization.

Study objective

We aim to study the efficacy of honey to prevent skin colonization with

microflora at central venous catheter insertion sites.

Study design

1. Prior to insertion of the catheter, a 3 x 3 cm area of skin at the catheter insertion site is sampled with a saline-moistened cotton swab which is quantitatively cultured to assess skin microflora.
2. Standard procedures will be performed for skin disinfection.
3. The 3x3 cm area of skin at the catheter insertion site is sampled again to assess colonization after skin disinfection.
4. Catheter is inserted according to standard procedures.
5. In the treatment group, medical grade honey is applied on a sterile gauze which is placed on the skin at the catheter insertion site. In the control group a gauze without honey will be applied. Subsequently, the catheter insertion sites are covered with standard wound dressing (Tegaderm®).
6. Catheter insertion site dressings will be changed on a daily basis. After removing the dressing, the skin will be sampled with saline-moistened cotton swabs to assess the colonization. Next, the insertion site will be disinfected according to standard intensive care procedures, and new dressings with or without honey will be applied.

Intervention

see 'study design'

Study burden and risks

During the insertion period of the catheter, a gauze with or without honey will be changed on a daily basis. Immediately prior to and after disinfection of skin before insertion of the catheter, and at daily dressing change, the skin will be sampled with saline-moistened cotton swabs to assess colonization.

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

admittance to Intensive Care for at least 48 h

Exclusion criteria

Infectious skin diseases
Other skin diseases that can be considered to influence microbial colonization
Immunosuppression by >5 mg prednisone daily, or any other immunosuppressive agent, in relation to organ transplantation or autoimmune disease

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2007
Enrollment:	270
Type:	Anticipated

Medical products/devices used

Generic name:	Revamil
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
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	NL17122.018.07