

Efficacy of medicinal honey to reduce skin colonization of intensive care patients

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Determine the efficacy of medical grade honey to reduce or prevent bacterial colonization at skin of intensive care patients.

Ethical review	Not approved
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON29755

Source

ToetsingOnline

Brief title

Honey to reduce skin 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, honey, IC patient, skin

Outcome measures

Primary outcome

Reduction in number of culture-positive skin segments

Reduction in number of bacteria colonizing skin segments

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pilot-study with healthy volunteers, we showed that medical grade honey strongly reduces colonization of forearm skin (unpublished data).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 skin colonization and prevention of catheter-associated infections.

Study objective

Determine the efficacy of medical grade honey to reduce or prevent bacterial colonization at skin of intensive care patients.

Study design

After the pilot study with healthy volunteers, we aim to assess the efficacy of medical grade honey for intensive care patients. The procedure is as follows:

1. Two areas of skin (3 x 3 cm) of each forearm are sampled with cotton swabs, which are quantitatively cultured to assess skin microflora prior to application of medical grade honey.
2. Two skin patches on the right forearm are disinfected and sampled again with cotton swabs to assess the efficacy of disinfection.
3. All four patches of skin are covered with standard wound dressing (Tegaderm®), two with and two without medical grade honey.
4. After 2 days, the wound dressings are removed and the skin under the dressings is sampled with swabs and quantitatively cultured. After this procedure all four skin patches are disinfected.

Intervention

see 'study design'

Study burden and risks

Four Tegaderm dressings will be applied on forearm skin, two with and two without medical grade honey. After 2 days the dressings will be removed. Prior to, and after two days incubation, the skin segments are sampled using a cotton swab to determine bacterial colonization.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 15
1105AZ Amsterdam
Nederland

Scientific

Academisch Medisch Centrum

Meibergdreef 15
1105AZ Amsterdam
Nederland

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

Defective immunity

Allergic reaction to Tegaderm dressing

fragile skin, e.g., due to corticosteroid treatment

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Will not start
Enrollment: 100
Type: Anticipated

Medical products/devices used

Generic name: Revamil
Registration: Yes - CE intended use

Ethics review

Not approved
Date: 21-02-2007
Application type: First submission
Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL13913.000.06