

# 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.

|                              |                                |
|------------------------------|--------------------------------|
| <b>Ethical review</b>        | Not approved                   |
| <b>Status</b>                | Will not start                 |
| <b>Health condition type</b> | Bacterial infectious disorders |
| <b>Study type</b>            | 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pilot-study with healthy volunteers, we showed that medical grade honey strongly reduces colonization of forearm skin (unpublished data).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

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### Scientific

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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

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 |