

Does extranasal colonization of the throat and perineal area with *Staphylococcus aureus* occur?

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The aim of this study is to determine whether *Staphylococcus aureus* colonizes the human throat and the perineal area independent of the nose.

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

Summary

ID

NL-OMON37698

Source

ToetsingOnline

Brief title

Throat and perineal *S. aureus* carriage.

Condition

- Bacterial infectious disorders

Synonym

endogenous *Staphylococcus aureus* infection, infection with a bacterium which belongs to the normal flora of individuals

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carriage, perineal area, Staphylococcus aureus, throat

Outcome measures

Primary outcome

- In the first phase of the study the endpoint is to define the natural S. aureus carriage state of the nose, the throat and the perineal area over a follow-up period of 12 weeks among a cohort of volunteers. At the end of this phase those volunteers who, considering the definition (chapter 6.2 of protocol), are categorized as non-carriers for S. aureus will stop participating. The remaining volunteers will be included in the second phase of the study.
- In the second phase the effect of nasal eradication of S. aureus (using nasal mupirocin) on nasal, throat and perineal carriage with S. aureus will be determined.

Secondary outcome

not applicable

Study description

Background summary

Carriage of S. aureus on extra nasal body sites is less well studied than that of the vestibulum nasi. Yet there are indications that extranasal culturing, in particular of the throat and perineal area, is at least of similar importance as nasal culturing alone to determine carriage rates. The question remains whether throat or perineal without nasal colonization with S. aureus occurs, and if so what is the incidence and what are the implications on decolonization strategies.

Study objective

The aim of this study is to determine whether *Staphylococcus aureus* colonizes the human throat and the perineal area independent of the nose.

Study design

We propose a two-phase prospective experimental follow-up study.

Intervention

Mupirocin treatment.

Study burden and risks

Volunteers will have no benefits by participation in this study. The results obtained by this study might have a profound impact on the application of decolonization strategies for MRSA/*S. aureus* in populations at risk.

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

Volunteers above the age of 18 years.

Exclusion criteria

Antibiotic usage in the last 4 weeks.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2012

Enrollment: 200

Type: Anticipated

Ethics review

Approved WMO

Date: 23-05-2012

Application type: First submission

Review commission:

METC Erasmus MC, Universitair Medisch Centrum Rotterdam
(Rotterdam)

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	NL40156.078.12