Wisselwerking tussen S. aureus en andere bacteriën in de neus

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26095

Source
Nationaal Trial Register

Brief title
MACOTRA

Health condition

S. aureus, staphylococcus aureus

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Microbiome composition of the nose

Secondary outcome

Not applicable

Study description

Background summary

Rationale: This study will investigate the interaction between host nasal microbiome and Staphylococcus aureus to elicit the influence of host factors on success of dominant MRSA clones.

Objective: To identify nasal microbial communities associated with Staphylococcus aureus carriage and study the influence over time of S. aureus-targeted decolonization treatment on these microbial communities.

Study design: Prospective interventional cohort study with 2 groups.

Study population: A total of 70 healthy Dutch volunteers will be recruited to participate in the study. These volunteers will be grouped based on their S. aureus carrier status, either as carriers or noncarriers.

Intervention: After inclusion and determination of carrier status, all volunteers will be treated with Mupirocin (Bactroban) 2% nasal ointment and Chlorhexidine gluconate (Hibiscrub®) 4% cutaneous body wash solution within the product indication and in accordance with local clinical practice.

Main study parameters/endpoints: Microbiome composition of the nose, to be analysed in relation to S. aureus carrier status and decolonization.

Study design

After a two-week screening period for S. aureus nasal carriage, eligible volunteers are included and followed for 6 months.

Intervention

5 day treatment with Bactroban 2% nasal ointment (mupirocin) and Hibiscrub 4% cutaneous solution (chlorhexidine gluconate) at the start of the study

Contacts

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Eligibility criteria

Inclusion criteria

Volunteers must be over 18 years old

Exclusion criteria

- Employee of the Erasmus MC

- Intermittent carrier of Staphylococcus aureus

- Use of drugs influencing microbiome in 3 months prior to the study period i.e. antibiotics, antiparasitics or
antifungals

- Regular use of commercial probiotics in 3 months prior to the study period

- Known allergy to components of the intervention treatment, consisting of mupirocin nasal ointment and chlorhexidine wash
- Pregnant and breastfeeding women, due to limited scientific evidence on adverse effects of mupirocin treatment during pregnancy and breastfeeding.

- Known chronic diseases affecting the immune system (such as diabetes mellitus, renal insufficiency, COPD,
heart diseases, immunocompromised status (HIV, AIDS), skin diseases such as severe

eczema or use of
immunosuppressant drugs

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48845
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7254
NTR-old	NTR7461
CCMO	NL65791.078.18
OMON	NL-OMON48845

Study results

Summary results
Not applicable