Carriage of S. aureus and interaction with the nasal microbiome

Published: 20-06-2018
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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

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

Summary

ID

NL-OMON48845

Source
ToetsingOnline

Brief title
MACOTRA

Condition

- Bacterial infectious disorders
- Skin and subcutaneous tissue disorders

Synonym
S. aureus carriage

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: carrier, interaction, microbiome, S. aureus

Outcome measures

Primary outcome

Microbiome composition of the nose, to be analysed in relation to S. aureus

carrier status and decolonization.

Secondary outcome

NA

Study description

Background summary

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.

Study 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

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.

Study burden and risks

Risks and burden are considered to be minimal. The nasal swabs and microbiome samples are considered non-invasive procedures and can cause no harm for the patient. Additionally, volunteers will be asked to fill out a questionnaire regarding risk factors for acquisition of Staphylococcus aureus and report changes during the study period. Medical products used in the intervention are registered at the CBG, used topically and used within the indication. The risk for usage of these medical products is considered equal for both S. aureus carriers as noncarriers. Overall risk for usage of these medical products is considered low, as the study population is healthy and the intervention medication has been used worldwide for years now without serious adverse reactions.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 (see Ch 5.1)
- 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2019
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Bactroban Nasal Ointment 2%
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Hibiscrub 4% w/v Cutaneous Solution
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-06-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2019
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-10-2019
Application type:	Amendment
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

ID: 26095
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2018-002119-81-NL
CCMO	NL65791.078.18
OMON	NL-OMON26095