

# Wisselwerking tussen S. aureus en andere bacteriën in de neus

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26095

### Source

NTR

### 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

## Public

Erasmus Medisch Centrum Rotterdam - Department of Medical Microbiology & Infectious diseases

Margreet C. Vos

Wytemaweg 80, Room Na-901k

Rotterdam 3015 CN  
The Netherlands  
0107033510

### **Scientific**

Erasmus Medisch Centrum Rotterdam - Department of Medical Microbiology & Infectious diseases

Margreet C. Vos  
Wytemaweg 80, Room Na-901k

Rotterdam 3015 CN  
The Netherlands  
0107033510

## **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:	Non controlled trial
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