# The role of immune evasion cluster (IEC) encoded proteins in Staphylococcus aureus (S. aureus) nasal colonisation

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This study aims to define the role of the IEC in S. aureus colonisation.

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

## Summary

#### ID

NL-OMON31142

**Source** ToetsingOnline

Brief title IEC study

## Condition

• Bacterial infectious disorders

Synonym Nasal colonisation S. aureus

**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:** Immune evasion cluster, Innate immunity, Nasal colonisation, Staphylococcus aureus

#### **Outcome measures**

#### **Primary outcome**

Difference between the strain with and without IEC in persistence on the nasal

epithelium in time. This is measured by counting the number of colony forming

units on blood agar plates after microbiological culture of the nostrils.

#### Secondary outcome

Not applicable

## **Study description**

#### **Background summary**

Staphylococcus aureus (S. aureus) permanently colonises the nose of about 20% of the healthy human population. Colonisation is a risk factor for subsequent infection. Still, little is known about the mechanisms defining S. aureus carriage. Recently a key role for Clumping factor B (ClfB), a S. aureus cell wall protein, was demonstrated. A role for the immune evasion cluster (IEC) is proposed in this study. The IEC is carried by

beta-hemolysin-converting-bacteriophages and is found predominantly in human S. aureus isolates. The IEC is formed by genes encoding four human specific innate immune evasion molecules, namely SCIN (Staphylococcal Complement INhibitor), CHIPS (Chemotaxis Inhibitory Protein S. aureus), SAK (Staphylokinase) and SEA (Staphylococcal Enterotoxin A). Therefore, it is hypothesised that S. aureus with an IEC is able to persist longer in the human nose than S. aureus without an IEC.

#### Study objective

This study aims to define the role of the IEC in S. aureus colonisation.

#### Study design

#### Experimental study.

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Week 1 Pre-study blood samples are collected. Nasal culture is obtained and questionnaire is filled in.

Week 2 Nasal cultures is repeated in order to differentiate between persistent, intermittent and non-carriers.

Week 3 Decolonisation treatment is started for all volunteers (nasal mupirocin twice daily for five days in combination with once daily washing with chloorhexidin containing soap [Hibiscrub®, Regent Medical, United Kingdom]). If a side effect of mupirocin is noted (allergic reaction or itching), the volunteer can no longer participate in this study.

Week 9 Five weeks after mupirocin and chloorhexidin treatment, nostrils are cultured again to assess colonisation status. If eradication of S. aureus was not successful, mupirocin treatment is repeated. The participant can participate in the study only if eradication is successful after one or two treatments.

Week 10 Artificial inoculation is performed. Both the S. aureus strains with and without IEC are cultured separately to log phase in TSB. An inoculum is prepared immediately prior to inoculation. In both the left and right nostril 1.10exp7 colony forming units (cfu\*s) are applied. In each individual volunteer, either the S. aureus with or without bacteriophage is installed. The latter is blinded and at random. Inoculation will take place under medical supervision. Participants receive hygienic advice. After inoculation, medical check up and culture of both nostrils separately is performed at day 1, 2, 3, 4, 7, 14, 21 and 28 to count the mean number of cfu\*s between the strain with respectively without IEC.

Week 14 End of study. Medical check-up all participants. A nasal, pharyngeal and rectal swab is obtained. All participants who still carry the inoculation strain are treated with mupirocin and are swabbed again after one week. A second blood sample is drawn.

#### Intervention

14 volunteers are inoculated with S. aureus strain 8325-4 with IEC (1.10exp7 colony forming units per nostril)

14 volunteers are inoculated with S. aureus strain 8325-4 without IEC (1.10exp7 colony forming units per nostril)

### Study burden and risks

The burden associated with participation is multiple visits to the Erasmus MC.

There are no risks associated with filling in the questionnaire and taking a nasal swab. The risk associated with the collection of blood is a hematoma and pain near the injection site. The risk associated with using mupirocin are its side effects: ichting and irritation. These side effects are rare, however. The risk of inoculation with S. aureus is a (skin)infection with S. aureus. However, a large proportion of healthy individuals carry S. aureus, without any

problems. Also, the strain that is used has little virulence. Moreover, in our previous inoculation studies there were no important infections seen.

## Contacts

#### Public

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## **Trial sites**

## **Listed location countries**

Netherlands

## **Eligibility criteria**

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

## **Inclusion criteria**

Healthy individuals older than 18 years The volunteer has given informed consent

## **Exclusion criteria**

Individuals with age below 18 years.

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Volunteers with diabetes mellitus, renal insufficiency, COPD, heart diseases, immunocompromised status (HIV, AIDS) or use of immunosuppressants, allergy for mupirocin or penicillin, skin diseases such as eczema and psoriasis. Volunteers who have close contact with individuals suffering from the afflictions mentioned above.

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	11-02-2008
Enrollment:	28
Туре:	Actual

## **Ethics review**

Approved WMO	
Date:	17-10-2007
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** CCMO ID NL19582.078.07