Dynamics of the innate, cellular and humoral immune response in healthy persistent, intermittent and noncarriers of Staphylococcus aureus

Published: 05-06-2007
Last updated: 08-05-2024

This study aims to identify qualitative and quantitative differences in innate, cellular and humoral immune response between persistent, intermittent and noncarriers of S. aureus.

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

Summary

ID

NL-OMON30541

Source
ToetsingOnline

Brief title
STAIR study

Condition

- Bacterial infectious disorders

Synonym
Nasal colonisation Staphylococcus 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: Antistaphylococcal Antibodies, Leukocytes, Nasal colonisation, Staphylococcus aureus

Outcome measures

Primary outcome

1. The amount of persistent, intermittent and noncarriers

2. The qualitative or quantitative difference in the presence of

antistaphylococcal IgG, IgM and IgA between healthy persistent, intermittent

and noncarriers of S. aureus in blood or nasal secretion

3. The qualitative or quantitative difference in the presence of CD4+ and CD8+

T cells between healthy persistent, intermittent and noncarriers of S. aureus

in blood

4. The difference in protein composition of nasal secretion between healthy

persistent, intermittent and noncarriers of S. aureus

5. The qualitative or quantitative difference in the presence of

antistaphylococcal antibodies and cellular immune response between healthy

individuals compared to patients with a bacteremia caused by S. aureus

Secondary outcome

Not applicable

Study description

Background summary

Staphylococcus aureus (S. aureus) is an important pathogen causing a variety of infections ranging from mild to life threatening in the community as well as in hospitals. The rise of MRSA has further increased the impact of S. aureus.

Carriers of S. aureus, about 20% of the healthy population, have an increased risk of developing S. aureus infection. Carriers even have a three fold higher risk for acquiring S. aureus bacteremia, but a significant lower risk of death due to bacteremia compared to noncarriers. An explanation for this observation has not been found yet, although a role for the immune response has been proposed. Due to long time exposure, carriers may have developed a certain level of immunity and possess protective antibodies and leukocytes. Noncarriers may possess other antibodies and leukocytes, which protects them from becoming a carrier. Infected patients are expected to display a high level of immune response. Still, little is known about if, and if so, which immune mechanisms are involved in S. aureus carriage and S. aureus infection however.

Study objective

This study aims to identify qualitative and quantitative differences in innate, cellular and humoral immune response between persistent, intermittent and noncarriers of S. aureus.

Study design

Cross sectional study. 400 healthy individuals are included.
On t0 a short questionnaire is filled in, a nasal swab and two bloodsamples are taken. On t1 (one week later) a nasal swab is taken and nasal secretion is collected.

Study burden and risks

The burden associated with participation is two short visits to the Erasmus MC. The first time (t0) a short questionnaire is filled in, a nasal swab and two bloodsamples are taken. Duration: 20 minutes.
One week later (t1) a nasal swab is taken and nasal secretion is collected. Duration: 15 minutes. Total duration of study: 35 minutes.

There are no risks associated with filling in the questionnaire, taking a nasal swab and collection of nasal secretion. The risk associated with the collection of blood is a hematoma and pain near the ejection site. An experienced person (not a student) will collect the sample.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230

3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

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
Volunteers with diabetes mellitus, renal insufficiency, COPD, heart diseases, immunocompromised status (HIV, AIDS) or use of immunosuppressants, skin diseases like eczema and psoriasis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2007
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2007
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	ID
CCMO	NL16312.078.07