Analyses of pathogen and host determinants in hospitalized patients with a laboratory confirmed Staphylococcus aureus infection: The PATHOS Study

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Objective: to study host and pathogen determinants of S. aureus infection to identify a putative antigen as target for the development of a prophylactic vaccine against S. aureus.

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

Summary

ID

NL-OMON31769

Source
ToetsingOnline

Brief title
PATHOS Study

Condition

- Bacterial infectious disorders

Synonym
sepsis, wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Wyeth
Source(s) of monetary or material Support: Wyeth Pharmaceuticals

Intervention

Keyword: host response, infection, pathogen response, Staphylococcus aureus

Outcome measures

Primary outcome

The identification of candidate antigens for development of a prophylactic S.

aureus vaccine.

Secondary outcome

Not applicable.

Study description

Background summary

Staphylococcus aureus is the leading nosocomial pathogen worldwide and poses an immense burden on health care. Nasal carriage of S. aureus is an important risk factor for infection in various patient populations. New interventions are needed to control S. aureus infection; a possible strategy is the development of a prophylactic vaccine. Analysis of host and pathogen determinants during early infection with S. aureus is the first step in selection of putative antigen targets for the development of a vaccine against S. aureus. To determine the severity of infection, bacterial DNA load and procalcitonine will be measured.

Study objective

Objective: to study host and pathogen determinants of S. aureus infection to identify a putative antigen as target for the development of a prophylactic vaccine against S. aureus.

Study design

Patiënts wit a laboratory confirmed Staphylococcus aureus bacteraemia or wound

infectie are eligible for the study. On days 2, 7 and 14 after the initial culture was obtained, blood will be drawn for antigen and antibody expression studies. For bacteriemic patients blood will also be drawn on days 3, 4 and 5. Also, two nose swabs will be taken on day two for determination of nasal carriage of S. aureus. All isolates will be stored and typing of these isolates will be done with AFLP analysis.

Study burden and risks

Blood for study purposes will be drawn simultaneously to drawing blood for routine clinical determinations according good clinical practice. No extra venapunction is involved with participation in the study, so no extra risks are involved for the patient. In general, obtaining nose swabs for culture of S. aureus is not considered to be of much discomfort and does not involve additional risks for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

-Adult patients (>18 years) with laboratory confirmed Staphylococcus aureus bacteraemia or wound infection. The diagnosis of S. aureus infection should be available within 48 hours after cultures were obtained. Patient should give informed consent prior to inclusion.

Exclusion criteria

-Incapacitated patients (Glasgow coma scale <15).
-Patients with neutropenia (<500 x10e6 neutrophils/L)
-Patients with haematological malignancy
-Known immunodeficiency (HIV, cytotoxic chemotherapy, transplantation, etc.).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2008

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL16899.029.07