

# Analyzes of pathogen and host determinants in hospitalized patients with a laboratory confirmed infection caused by *Staphylococcus aureus*: the PATHOS Study.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20533

### Source

Nationaal Trial Register

### Brief title

PATHOS Studie

### Health condition

English: *Staphylococcus aureus*, vaccine, antigen, determinant

Dutch: *Staphylococcus aureus*, vaccin, antigeen, determinant

## Sponsors and support

**Primary sponsor:** Wyeth Pharamceuticals B.V.

**Source(s) of monetary or material Support:** Wyeth Pharamceuticals B.V.

## Intervention

## Outcome measures

### Primary outcome

Putative antigen targets for the development of a *Staphylococcus aureus* vaccine.

### Secondary outcome

N/A

## Study description

### Background summary

*Staphylococcus aureus* is the leading nosocomial pathogen worldwide. Nasal carriage is an important risk factor for spread of endogenous en exogenous infection with this bacteria. The development of a prophylactic vaccine against *S. aureus* infection is one of the possible interventions to control infection with this pathogen. To select putative antigens for the development of such a vaccine, antigen and antibody expression profiles should be studied during natural infection with *S. aureus*.

In this study we aim to study pathogen and host determinants of *S. aureus* infection by collecting blood samples and nasal swabs from patients with a *S. aureus* bacteraemia or wound infection to study host and pathogen determinants of *S. aureus* natural infection.

The study will be conducted at the VU University Medical Center in Amsterdam and the Amphia Hospital in Breda. Only adult patients will be recruited and those who are incapacitated or have underlying immunological disease are excluded. Recruitment of patients will start at the beginning of November and will probably be completed by the end of February.

### Study objective

To identify candidate antigens for the development of a prophylactic *Staphylococcus aureus* vaccine by studying expression profiles of host and pathogen determinants during natural infection.

### Study design

N/A

### Intervention

Blood will be drawn at days 2, 7 and 14 after the moment that the initial blood and wound cultures were obtained. This will be done simultaneously to drawing blood for routine haematology and chemistry investigations according good clinical practice, so no extra venapuncture is required for participation in the study.  
At day 2 two nasal swabs will be obtained for assessment of *Staphylococcus aureus* nasal carriage.

## Contacts

### **Public**

VU University Medical Center  
Department of Medical Microbiology & Infection Control  
P.O. Box 7057  
J.A.J.W. Kluytmans  
Amsterdam 1007 MB  
The Netherlands  
+31 20-4440552

### **Scientific**

VU University Medical Center  
Department of Medical Microbiology & Infection Control  
P.O. Box 7057  
J.A.J.W. Kluytmans  
Amsterdam 1007 MB  
The Netherlands  
+31 20-4440552

## Eligibility criteria

### **Inclusion criteria**

1. Adult patients (>18 years) with *S. aureus* bacteraemia or wound infection;
2. Diagnosis of *S. aureus* infection within 48 hours after initial cultures;
3. Informed consent.

### **Exclusion criteria**

1. Incapacitated patients (GSC<15);

2. Patients with neutropenia ( $< 500 \times 10^6$  neutrophils/L);
3. Patients with haematological malignancy;
4. Transplantation patients;
5. Patients who are treated with immunosuppressive drugs.

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007
Enrollment:	50
Type:	Actual

## Ethics review

Not applicable	
Application type:	Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

4 - Analyzes of pathogen and host determinants in hospitalized patients with a labor ... 13-05-2025

**Other (possibly less up-to-date) registrations in this register**

No registrations found.

**In other registers**

Register	ID
NTR-new	NL1006
NTR-old	NTR1035
Other	: N/A
ISRCTN	ISRCTN19709160

**Study results**