

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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20533

Source

NTR

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

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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.

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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