

Analyses of PATHogen and HOST determinants in hospitalised patients with a laboratory confirmed infection caused by Staphylococcus aureus: the PATHOS study

Submission date 05/09/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 05/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title**Acronym**

PATHOS study

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre, non-randomised, non-controlled, single armed clinical trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Staphylococcus aureus infection and vaccination

Interventions

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.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/03/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Incapacitated patients (Glasgow Coma Scale [GSC] less than 15)
2. Patients with neutropenia (less than 500×10^6 neutrophils/L)
3. Patients with haematological malignancy
4. Transplantation patients
5. Patients who are treated with immunosuppressive drugs

Date of first enrolment

01/11/2007

Date of final enrolment

01/03/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Vrije University Medical Centre

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

Wyeth Pharmaceuticals B.V. (The Netherlands)

ROR

<https://ror.org/02bzf1224>

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration