

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 <input type="checkbox"/> Protocol
Registration date 05/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/09/2007	Condition category Infections and Infestations	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/11/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

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)

Sponsor details

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info-nl@wyeth.com

Sponsor type

Industry

Website

<http://www.wyeth.nl/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration