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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/09/2007	**Overall study status** Completed	
Last Edited 05/09/2007	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 500x 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)

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Sponsor type
Industry

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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