Advanced understanding of Staphylococcus aureus and Pseudomonas aeruginosa Infections in EuRopE * Intensive Care Units (ICU)

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To estimate the incidence of S. aureus and P. aeruginosa ICU pneumonia, especially VAP, and to assess its association with patient-related and contextual factors, e.g. colonization status, serum antibody levels against S. aureus alpha toxin [AT],...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON43881

Source
ToetsingOnline

Brief title
ASPIRE-ICU

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
lower respiratory tract infection, lung infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Europese subsidie. Innovatives Medicine Initiative (IMI);grant no. 115523

Intervention

Keyword: Colonization, ICU Pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus

Outcome measures

Primary outcome

The primary outcomes are the incidence of S. aureus ICU acquired pneumonia and

the incidence of P. aeruginosa ICU acquired pneumonia through ICU stay.

Secondary outcome

- colonization with S. aureus at ICU admission

- colonization with P. aeruginosa at ICU admission

- mortality through day-90 post ICU admission

- time to primary outcomes in days

Study description

Background summary

Intensive Care Unit (ICU) acquired pneumonia, including ventilator-associated pneumonia (VAP), is a frequently occurring health-care associated infection (HAI), which causes considerable morbidity, mortality and health care costs. Important pathogens causing ICU pneumonia are Staphylococcus aureus and Pseudomonas aeruginosa. The epidemiology of ICU pneumonia and patient-related and contextual factors is not fully described, but is urgently needed to support the development of effective interventions.

Study objective

To estimate the incidence of S. aureus and P. aeruginosa ICU pneumonia, especially VAP, and to assess its association with patient-related and

contextual factors, e.g. colonization status, serum antibody levels against S. aureus alpha toxin [AT], the P. aeruginosa PcrV / Psl virulence factors.

Most important secondary objectives:
a) To develop a risk prediction model to quantify the risk of acquiring S. aureus ICU pneumonia during ICU stay, by using a composite score of independent risk factors identified through primary objective.
b) To develop a risk prediction model to quantify the risk of acquiring P. aeruginosa ICU pneumonia during ICU stay, by using a composite score of independent risk factors identified through primary objective.

For a comprehensive overview of all secondary and exporatory objectives, see chapter 3 in the ASPIRE-ICU protocol.

Study design

ASPIRE-ICU is a prospective observational, multicenter, epidemiologic cohort study nested within routine surveillance among ICU patients in Europe. A group of 2000 eligible patients will be consented and enrolled as subjects into a study cohort in which active sampling and more elaborate data collection will take place. Throughout the whole study, fully anonymized, basic surveillance data will be captured of all ICU patients as a part of routine practice and will serve to assess ubiquity of the results across the groups.

Study burden and risks

This research in (mostly) incapacitated adults, is in our opinion associated with a minimal risk and minimal burden for participating subjects. All study procedures are of frequent occurrence on the ICU and are often already carried out daily as part of routine care. Where possible, will these procedures be combined with the routine taking of samples, ensuring that the subject is not exposed to additional risk or burden.
Considering the disease that is studied in this research (ICU pneumonia) it is not possible to do this research in a population with capacitated (non-ventilated) subjects. Especially this patient group is at highest risk for this infection, and a study that would only include capacitated ICU patients would not give representative risk factors applying to the vulnerable, incapacitated population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Participant is 18 years or older at the time of enrollment.
2. Participant is on mechanical ventilation at ICU admission, or is (expected to be) within 24 hours thereafter, based on investigator*s judgment.
3. Expected stay in ICU is 48 hours or longer based on investigator*s judgment.
4. SA colonization status is known within 72 hours after start of first episode of mechanical ventilation ICU admission and according to the result the patient qualifies for enrollment (see section 4.1).
5. Written informed consent from subject / legally accepted representative within 72 hours after start of first episode of mechanical ventilation.

Exclusion criteria

1. Previous participation as a subject in the study cohort of this study.
2. Simultaneous participation of the subject in any preventive experimental study into anti-staphylococcus or anti-pseudomonas aeruginosa interventions.
3. Expected death (moribund status) within 48h or ICU discharge of the participant within 24h, at the moment of informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	26-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02413242
CCMO	NL51762.041.14