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Procalcitonin for discontinuation of antibiotic therapy in clinically diagnosed Ventilator Associated Pneumonia

Submission date	Recruitment status	[_] Prospectively registered
11/08/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2011	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym

The ProVAP pilot study

Study objectives
We hypothesise that a Procalcitonin (ProCT) guided approach will increase the number of antibiotic-free days (for Ventilator Associated Pneumonia [VAP]) alive at 28 days by one third without compromising clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for the Protection of Human Subjects in Research (FWA #00004009, docket #H-11990), EKBB Switzerland

Study design
Prospective multicentre randomised controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ventilator associated pneumonia

Interventions
In this study, all patients, irrespective of the randomisation group, will be treated with antibiotics for 72 hours.

1. In patients randomly assigned to the standard therapy group, antibiotics will be prescribed and discontinued based on the clinical stability, radiologic and laboratory findings as routinely performed in the treating facility. Serum and/or plasma samples for ProCT will be collected daily, and the treating physician will be blinded to the results of the ProCT level.

2. In patients randomly assigned to the ProCT group, the decision to discontinue antibiotic therapy will also be based on the clinical stability, radiologic and laboratory findings. However, in this group, a further assessment of the probability of bacterial infection using ProCT levels will be available. Antibiotic discontinuation will be recommended according to serum ProCT concentrations as follows:
2.1. strongly encouraged if less than 0.25 ug/L
2.2. encouraged if less than 0.5 ng/ml or a decrease more than or equal to 80% as compared to day zero values (or previous values)
2.3. discouraged if more than or equal to 0.5 ng/ml or a decrease less than or equal to 80% as compared to day zero values (or previous values)
2.4. strongly discouraged if more than or equal to 1 ug/L

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
Number of antibiotic free-days (for VAP) alive within 28 days of clinically suspicion of VAP.

Key secondary outcome(s))
1. Clinical deterioration (defined as an increase in Clinical Pulmonary Infection Score [CPIS] of more than two points)
2. Microbiologically documented pulmonary infection recurrence
3. The evolution of signs and symptoms potentially linked to pulmonary infection (fever, leukocyte counts, partial pressure of oxygen in arterial blood [PaO2]/fraction of inspired oxygen [FiO2], and radiological infiltrates)
4. Number of mechanical ventilation-free days at 28 days
5. The length of stay in the ICU within 30 days
6. In-hospital mortality up to 30 days
7. Mortality at 30 days
8. Percentage of patients in the ProCT group for whom treatment recommendations are followed
9. Correlation of other biomarkers and clinical course

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Intensive Care Unit (ICU) patients who are intubated and have been mechanically ventilated for at least 48 hours
2. 18 years of age and older
3. Clinical suspicion of VAP based on clinical and radiological criteria (new or progressive radiographic infiltrate) plus at least two of three clinical features:
3.1. fever greater than 38°C
3.2. leukocytosis or leucopenia
3.3. purulent tracheal secretions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Patients with coexisting, documented extrapulmonary infection diagnosed between days one and three that requires antibiotic therapy longer than three days
3. Previous long-term corticosteroid therapy (more than or equal to 0.5 mg/kg per day of prednisolone or equivalent for more than one month)
4. Severe immunosuppression (solid organ transplantation or stem cell transplant recipients, known Human Immunodeficiency Virus [HIV] infection, neutropenic patients and patients after chemotherapy)

Date of first enrolment
01/07/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
University/education

Funder Name
University Hospital Basel (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	01/10/2011		Yes	No