Reduction of antibiotic use in the ICU: Procalcitonin guided versus conventional antibiotic therapy in patients with sepsis in the ICU

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Is the duration of Procalcitonin guided antibiotic therapy shorter than standard antibiotic therapy in patients with sepsis admitted to the ICU and treated with antibiotics

Ethical review	Not approved
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33222

Source
ToetsingOnline

Brief title
Procalcitonin in the ICU

Condition

- Bacterial infectious disorders

Synonym
Sepsis, Septicemia

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: BRAHMS,Stichting vrienden van het Alysis

Leerhuis

Intervention

Keyword: Antibiotic therapy, Intensive Care, Procalcitonin, Sepsis

Outcome measures

Primary outcome

· Duration of antibiotic therapy

· Antibiotic free days

Secondary outcome

· 28 day mortality

· In hospital mortality

· ICU LOS

· Hospital LOS

· Clinical Cure

· Reoccurrence of initial infection

· Nosocomial superinfection

Study description

Background summary

The adequacy of early empiric antimicrobial therapy is an important factor in determining the outcome in patients with severe sepsis. In hospitalized patients with community acquired pneumonia, early administration of adequate antimicrobial therapy determines patient outcome. The duration of adequate antibiotic therapy in these patients however is less clear. In hospitalized patients with mild to moderate-severe community acquired pneumonia(CAP), 3 day antibiotic treatment is clinical as effective as 8 day treatment. Comparing 8 and 15 days of appropriate antibiotic therapy in ICU patients with ventilator associated pneumonia (VAP) shows comparable clinical efficacy and mortality accompanied with a significant reduction in antibiotic-free days. An antibiotic

discontinuation policy in the ICU based on predetermined criteria (noninfectious etiology established, temperature < 38.3ºC, white cell count <10 or decreased by >25% from peak value, improvement of chest X-ray, absence of purulent sputum, PaO2/FiO2 ratio >250) showed similar efficacy associated with a two day reduction in antibiotic treatment. Duration of antibiotic therapy in patients with sepsis in the ICU based on inflammatory markers has not been extensively studied.
Procalcitonin (PCT) is an acute phase protein that has prognostic value in critically ill patients and can be used to monitor disease activity in sepsis and systemic inflammation. Increase in serum PCT levels is associated with a high risk of mortality while a PCT decrease is a strong predictor of survival.
PCT guided antibiotic therapy has been shown to significantly reduce antibiotic use in hospitalized patients with lower respiratory tract infections ,community acquired pneumonia or sepsis without a reduction in efficacy. In patients with sepsis there is also a significant reduction in ICU length of stay.
Cost-effectiveness of PCT guided antibiotic therapy is expected when reduction of ICU length of stay is taken into account.

Study objective

Is the duration of Procalcitonin guided antibiotic therapy shorter than standard antibiotic therapy in patients with sepsis admitted to the ICU and treated with antibiotics

Study design

Monocenter prospective randomized controlled unblinded clinical trial

Intervention

PCT guided antibiotic therapy in the intervention goup, standard antibiotic therapy in the control group

Study burden and risks

No extra burden. In the control group risk of superinfection, resistant microorganisms, prolonged length of stay. In the intervention group disease recurrence.

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. Patients admitted to the ICU
2. Age >18 years
3. Antibiotic therapy for sepsis with a suspected or proven focus of infection

Exclusion criteria

1. Age <18 years
2. Pregnancy
3. Infection or presumed infection requiring prolonged antibiotic therapy (osteomyelitis, meningitis, endocarditis, septic arthritis, mediastinitis, tuberculosis, Pneumocystis jiroveci pneumonia, Toxoplasmosis, Legionellosis, Listeriosis)
4. Indication for prolonged systemic prophylactic antibiotic therapy
5. Severe viral or parasitic infections (hemorrhagic fever, malaria)
6. Antibiotic therapy started 48 hours before enrollment
7. Severe immunocompromised patients (AIDS with a CD4 count<200cells/mm3, severe neutropenia(<500 neutrophils/mm3), patients undergoing immunosuppressive therapy after solid organ transplantation)

8. Patients foregoing lifesustaining treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	24-09-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
CCMO	NL28773.000.09