The effect of two dosing regimens cefotaxime on the presence of potential pathogenic micro-organisms in airways.

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Is treatment A: cefotaxime parenteral twice daily 1 gram during four days as effective as treatment B: cefotaxime parenteral four times daily 1 gram in preventing airway colonisation by potential pathogenic microorganisms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON33091

Source
ToetsingOnline

Brief title
The effect of two dosing regimens cefotaxime in the context of SDD.

Condition

- Respiratory tract infections

Synonym
in potential harmful bacteria, potential pathogenic microorganisms

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: cefotaxime, potential pathogenic microorganism, SDD

Outcome measures

Primary outcome

The primary study parameter is airway colonisation by potential pathogenic microorganisms after four days of selective decontamination of the digestive tract.

Secondary outcome

Secondary study parameters are length of stay on the ICU, length of stay in the hospital, ICU mortality, hospital mortality, duration of mechanical ventilation and pneumonia during ICU admission following the criteria of the Centers for Disease Control.

Study description

Background summary

Selective decontamination of the digestive tract (SDD) is a strategy that aims to prevent 2 types of endogenic pneumonia caused by endogenic flora of the digestive tract or hospital acquired nosocomial bacteria. Primary endogenic pneumonia, the most common infection on the ICU, can only be prevented by administering parenteral antibiotics (cefotaxime) directly at admission. At the moment cefotaxime 4 times a day 1 gram during 4 days is the antibiotic of choice in the Netherlands. After 4 days the parenteral antibiotic is whitdrawed, as it is shown that the majority of patients have no airway colonisation of potential pathogenic microorganisms after 4 days. From this moment on the oral antibiotics of the SDD regime have their effect. SDD is a profylactic regime, not a therapeutic regime. Interesting in this context is that pneumonia can be treated effectively with cefotaxime twice daily 1 gram. This dose regime has not been tested in the context of SDD.

Study objective

Is treatment A: cefotaxime parenteral twice daily 1 gram during four days as effective as treatment B: cefotaxime parenteral four times daily 1 gram in preventing airway colonisation by potential pathogenic microorganisms.

Study design

The study design is a randomised single blind study at an intensive care unit during a period of two years. Patients are assigned to group A or group B by randomisation. Patients assigned to group A will receive cefotaxime two times a day and a placebo two times a day during four days. Patients assigned to group B will receive cefotaxime four times a day during four days (standard therapy). On the first day (before supplementing the study therapy) and on the fourth day cultures of endotracheal aspirates and oropharynx are obtained. The presence of potential pathogenic microorganisms in the cultures will be compared between the two study groups.

Study burden and risks

The burden of participation is small for the patient, since culture collection is part of the standard therapy.

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

All patients expected to be intubated for more than 24 hours.
All non-intubated patiënts who are expected to receive enteral tube feeding for more than 48 hours.

Exclusion criteria

Pneumonia at admission on the ICU
Expected death within 48 hours
Immunocompromised patients
Pregnancy
Antibiotic therapy within the last 48 hours before admission at the ICU
No informed consent within 24 hours after admission at the ICU
Cephalosporin allergy
ICU admission in the previous 30 days
Age below 18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2010
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL28078.098.09