SDD-SOD-trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26718

Source
NTR

Brief title
SDD-SOD-trial

Health condition

Patients treated in Intensive Care Units.

Sponsors and support

Primary sponsor: participating centers, Dutch SDD Trialists Group
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

1. Hospital mortality;

2. ICU-mortality.

Secondary outcome

1. Prevalence of antibiotic resistance;

2. Duration of mechanical ventilation;

3. Duration of ICU-stay;

4. Incidence of hospital infections;

5. Antibiotic use;

6. Health care costs.

Study description

Background summary

Most ICU-acquired infections are caused by aerobic potentially pathogenic microoorganisms (PPM), usually after the development of colonisation. Colonisation with PPM occurs rapidly in the majority of patients.
The reservoirs of these bacteria are the digestive tract, other colonized patients and contaminated environments. Antibiotics pose a risk for subsequent colonization because these agents may eradicate the commensal flora of the host, thereby facilitating colonization with PPM.
The concept of colonisation resistance suggests a beneficial effect of the anaerobic flora in resisting colonisation by PPM along the digestive tract. SDD aims to selectively eliminate PPM and yeasts from the oropharyngeal cavity and gastrointestinal tract without disturbing the anaerobic flora.

The proposed benefits of SDD include the prevention of primary and secondary endogenous infections and the limitation of resistance development by eleminating the intestinal reservoir of gram-negative bacteria.
Since 1984 more than 30 randomized clinical trials and 8 mata-analyses on SDD in intensive care patients have been performed. Although most individual studies and all meta-analysesdemonstrated reductions in ventilator associated pneumonia (VAP), the beneficial effects on secondary outcomes were less evident. Only one single center study showed beneficial effect both on mortality and delvelopment of antibiotic resistance.
A point of concern is the possibility of emergence of antimicrobial resistance due to the excessive use of antibiotics. finally, four studies suggested that oropharyngeal decontamination (without systemic or intestinal prophylaxis) was as efficacious as the complete SDD regimen for preventing VAP.

Study objective

Can mortality in ICU-patients be reduced by using SDD or SOD as infection prevention measure, without increasing the development of antibiotic resistance.

Study design

N/A

Intervention

Selective Digestive Decontamination.

Selective Oropharyngeal Decontamination.

Contacts

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Eligibility criteria

Inclusion criteria

All patients admitted to the ICU with an expected stay> 72 hours in ICU or with an expected duration of mechanical ventilation > 48 hours.

Exclusion criteria

1. Known allergy to study-medication in patient-history;

2. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2004
Enrollment:	3450
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
Application type:	First submission

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
NTR-new	NL240
NTR-old	NTR278
Other	: N/A
ISRCTN	ISRCTN35176830

Study results

Summary results
N/A