The effects of SDD and SOD on antibiotic resistance in the ICU.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28926

Source
NTR

Brief title
N/A

Health condition

SDD, SOD, ICU, antibiotic resistance, selective decontamination

Sponsors and support

Primary sponsor: University Medical Center Utrecht,
Heidelberglaan 100, 3584 CX, Utrecht
phone +31 (0)887555555
Source(s) of monetary or material Support: University Medical Center Utrecht,
Heidelberglaan 100, 3584 CX, Utrecht
phone +31 (0)887555555

Intervention

Outcome measures

Primary outcome

Point prevalence of rectal and respiratory colonization with specificantly defined resistant

bacteria (both Gram positive and Gram negative) according to the WIP-guidelines.

Secondary outcome

1. ICU-admission until 48 hours after ICU-discharge, and microbiologically documented;

2. Rate of ICU-acquired bacteraemia caused by antibiotic resistant bacteria, expressed as the rate per 100 ICU-acquired bacteraemia caused by all pathogens;

3. Mortality; at day 28, ICU- and in-hospital mortality;

4. Length of ICU-stay;

5. Predefined subgroup analysis: mortality (28 days-, IC- and in-hospital mortality) in two subgroups: surgical and non-surgical patients;

6. Annual use of antibiotics based on pharmacy records.

Study description

Background summary

Multicenter, cross-over comparison study of SDD and SOD in ICU settings using either SDD or SOD for standard care. Results from routinely performed clinical and surveillance cultures will be used to assess development of antibiotic resistance in different ‘marker’ pathogens.

Study objective

The difference between both interventions is the absence of intestinal decontamination during SOD and the standard use of cephalosporins for all patients during SDD. It has been hypothesized that eradication of the intestinal Gram negative bacterial flora reduces the likelihood of resistance development in Gram negative bacteria.

Study design

Each ICU will be randomized into one of two study arms, starting either with SDD or SOD for twelve months, with cross-over to the other intervention. Before starting the first study period and after the
first period, a wash-out wash-in period (1 month) will be carried out, during which the new treatment (either SDD or SOD) will be implemented, but patient data will not be used for analysis.

Intervention

SDD consists of an oropharyngeal application (every 6 h) of a paste containing colistine, tobramycin and amphotericin B each in a 2% concentration, and administration (every 6 h) of a 10 ml suspension containing colistine, tobramycin and amphotericin B via the nasogastric tube. Topical antibiotics will be applied until ICU-discharge. In addition, cefotaxime (1000 mg, every 6 h) will be administered intravenously during the first four days of study.
SOD consists of oropharyngeal application of the same paste as used for SDD.

Contacts

Public
University Medical Center Utrecht,
Department of Medical Microbiology,
Postal address G.04.5.17
E. Oostdijk
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 7555006
Scientific
University Medical Center Utrecht,
Department of Medical Microbiology,
Postal address G.04.5.17
E. Oostdijk
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 7555006

Eligibility criteria

Inclusion criteria

Patients admitted to ICU with an expected length of ICU stay of 48 hours.

Exclusion criteria

Patients younger than 18 years.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	6000
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1679
NTR-old	NTR1780
Other	MEC UMC : 08/097
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A