

# Antibiotic resistance after usage of Selective Decontamination of the Digestive tract (SDD) or Selective Oropharyngeal Decontamination (SOD).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22794

### Source

NTR

### Brief title

Recolonisation trial

### Health condition

Antibiotic resistance, Selective Decontamination of the Digestive tract (SDD), Selective Oropharyngeal Decontamination (SOD), Intensive Care Unit (ICU)

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center

Postbus 9600, 2300 RC Leiden

The Netherlands

**Source(s) of monetary or material Support:** Leiden University Medical Center

Postbus 9600, 2300 RC Leiden

The Netherlands

## Intervention

## Outcome measures

### Primary outcome

Rectal colonization with any resistant aerobic Gram-negative bacteria at any time point within 10 days after ICU discharge.

### Secondary outcome

N/A

## Study description

### Background summary

N/A

### Study objective

Usage of SDD or SOD has been shown to reduce the incidence of ventilator associated pneumonia (VAP) and to improve patient survival.

SDD and SOD were shown not to increase resistance of bacteria colonizing the digestive tract. It can not be excluded that antibiotics in the faeces suppress the growth of resistant bacteria during SDD, and that those resistant strains may quickly re-emerge after discontinuation of SDD. The rate of re-colonization with resistant enteral bacterial flora after cessation of SDD or SOD is currently unknown.

To determine factors associated with emergence and persistence of pathogenic Gram-negative bacteria and to assess the rate of return of resistant enteral bacterial flora after treatment with SDD or SOD a follow-up study will be performed of rectal cultures of patients after discharge from the ICU at determined intervals.

### Study design

Days 0, 3, 6 and 10 after discharge from the ICU.

### Intervention

Rectal cultures after usage of either Selective Decontamination of the Digestive tract (SDD) or Selective Oropharyngeal Decontamination (SOD).

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

All adult ICU patients treated with either SDD or SOD for more than 4 days (96hrs).

### Exclusion criteria

1. Patients younger than 18 years of age;
2. Patients treated with enteral antibiotics other than SDD or SOD during ICU-stay.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	1240
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	28-02-2012
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	NL3167
NTR-old	NTR3311
Other	CME LUMC : 10 V006
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Study results

## Summary results

N/A