# SDD-SOD-trial.

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26718

**Bron**
NTR

**Verkorte titel**
SDD-SOD-trial

**Aandoening**

Patients treated in Intensive Care Units.

### Ondersteuning

**Primaire sponsor:** participating centers, Dutch SDD Trialists Group
**Overige ondersteuning:** N/A

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

1. Hospital mortality;<br>
2. ICU-mortality.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

Selective Digestive Decontamination.

Selective Oropharyngeal Decontamination.

# Contactpersonen

## Publiek

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Pregnancy.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-05-2004 |
| Aantal proefpersonen: | 3450 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 06-09-2005 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL240 |
| NTR-old | NTR278 |
| Ander register | : N/A |
| ISRCTN | ISRCTN35176830 |

# Resultaten

**Samenvatting resultaten**
N/A