

Selective Digestive Decontamination (SDD) - Selective Oropharyngeal Decontamination (SOD) trial

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/03/2011

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://jc.med.uu.nl/sdd>

Contact information

Type(s)

Scientific

Contact name

Dr Anne Marie G A de Smet

Contact details

University Medical Center Utrecht, AZU

PO Box 85500

Amsterdam

Netherlands

3508 GA

+31 (0)30 2509111

a.desmet@azu.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

SDD-SOD-trial

Study objectives

Can mortality in intensive care unit (ICU) patients be reduced by using SDD or SOD as infection prevention measure, without increasing the development of antibiotic resistance?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Infection in ICU patients

Interventions

Selective Digestive Decontamination.

Selective Oropharyngeal Decontamination.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Hospital mortality
2. ICU-mortality

Secondary outcome measures

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.

Overall study start date

01/05/2004

Completion date

24/07/2006

Eligibility

Key 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

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

3,450

Key exclusion criteria

1. Known allergy to study-medication in patient-history
2. Pregnancy

Date of first enrolment

01/05/2004

Date of final enrolment

24/07/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht, AZU

Amsterdam

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Centre Utrecht (Netherlands)

Sponsor details

PO Box 85500

Utrecht

Netherlands

3508 GA

Sponsor type

University/education

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Other

Funder Name

Dutch SDD Trialists Group (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009		Yes	No
Results article	survery results	01/01/2010		Yes	No
Results article	11 results	01/05/2011		Yes	No