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

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/03/2011	Infections and Infestations	

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
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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
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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