ISRCTN75875670 https://doi.org/10.1186/ISRCTN75875670

Endotracheal Suctioning: open or closed?

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 31/05/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR770

Study information

Scientific Title

Prevention of cross-transmission of antibiotic-resistant pathogens by using closed instead of open endotracheal suction systems in mechanically ventilated intensive care patients

Acronym
ES-trial

Study objectives
Cross-transmission of antibiotic-resistant pathogens can be prevented by using closed suction systems (CSS) instead of open suction systems (OSS) in mechanically ventilated intensive care unit (ICU) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethical Review Committee, University Medical Center Utrecht (in Dutch: Medisch Ethische Toetsingscommissie, Universitair Medisch Centrum Utrecht) on September 28, 2006 (ref: 05/311-C).

Study design
Randomised, controlled, crossover multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mechanical ventilation, complications

Interventions
Endotracheal suctioning as indicated, according to a protocol, with either CSS or OSS.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Occurrence of cross-transmission (primary endpoint), defined as acquired colonisation with a genetically identical pathogen with an epidemiological linkage to a potential source patient.

Secondary outcome measures
1. Length of stay in ICU
2. Antibiotic use
3. Cardio-respiratory adverse events (hypoxaemia, cardiac arrhythmia, damage to respiratory mucosa)
4. Mortality
5. The incidence of ventilator-associated pneumonia (VAP) and cost-efficacy

Overall study start date
01/12/2006

Completion date
01/03/2008

Eligibility

Key inclusion criteria
All adult ICU patients receiving mechanical vetilators (MV) will be included and, during six months, be subjected to the same endotracheal suctioning (ES)-procedure.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
No exclusion criteria. Preference of ES system is often based on assuptions, there is currently no scientific evidence available to prefer one system over the other.

Date of first enrolment
01/12/2006

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details
Department of Intensive Care
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The 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	meta-analysis results	01/01/2007		Yes	No
Results article	results	01/12/2012		Yes	No