Endotracheal Suctioning: open or closed?

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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