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A comparison of early versus late tracheostomy after intubation for critically ill patients on long-term ventilation.

Submission date 23/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/02/2010	**Overall study status** Completed	
Last Edited 19/02/2010	**Condition category** Surgery	

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
N/A

Study information

Scientific Title
A prospective randomised trial to compare the effects early versus late Percutaneous Dilatational Tracheostomy (PTD) after incubation on the rate of Ventilator-Associated Pneumonia (VAP), mortality and other factors in critically ill patients on long-term ventilation.

Study objectives
Long-term ventilation in intensive care units is associated with several problems such as increased mortality, increased rates of ventilator associated pneumonia (VAP), prolonged time of hospitalisation, and thus, leads to enormous financial consequences. While the influence of tracheostomy on VAP incidence, duration of ventilation, and time of hospitalisation has already been analyzed in several studies, the point of timing of the tracheostomy procedure on patient's mortality is still controversial. Within 2 years, 100 critically ill, mainly surgical patients entered this prospective randomized study. A percutaneous dilatational tracheostomy (PDT) was performed either early (4 days after intubation, 2.8 days median) or late (more than 6 days after intubation, 8.1 days median) after intubation. We compared both groups concerning outcome, VAP incidence and duration of hospitalisation and ventilation. This was a cross-departmental trial with collaboration between the Dept. of Anaethesiology, Dept. of Surgery Dept. of Neurosurgery and Dept. of Neurology.

Hypotheses:
1. Early tracheostomy is associated with a decreased mortality in critically ill surgical patients.
2. Early PDT performance, in comparison with late tracheostomy, is associated with decreased rates of VAP, duration of ventilation and time of hospitalization both in hospital and in (Intensive Care Units (ICUs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received by the Ethics board of the University Hospital of Giessen, Germany in January 2005.

Study design
Single centre cross-departmental prospective randomised active controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Intensive Care Units (ICUs); Percutaneous Dilatational Tracheostomy (PTD); ventilatory support

Interventions
After intubation patients either entered the early (ET) or the late tracheostomy (LT) trunk of this study:
In ET patients a percutaneous dilatational tracheostomy was performed within 4 days after intubation/trauma/surgery in LT patients the same procedure was performed after more than 6 days of intubation.
The Acute Physiology And Chronic Health Evaluation II (APACHE II) score was used to define the severity of the trauma. In each group 25 patients with APACHE II < 25 and > 25 were recruited.

Patients were followed until discharged from the hospital or rehabilitation centre.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. VAP as defined by
1.1. Clinical Pulmonary Infection Score (CPIS)
1.2. Sequential Organ Failure Assessment (SOFA) score
2. APACHE II score
3. Simplified acute physiology score (SAPS)
4. Temperature
5. Laboratory values
5.1. C-Reactive Protein (CRP)
5.2. Leukocytes
6. Thoracic X-ray
7. Days in ICU/hospital
8. Hours of ventilatory support

APACHE II score was measured at baseline, all other outcomes were measured daily.

Secondary outcome measures
None

Overall study start date
02/01/2005

Completion date
02/01/2007

Eligibility

Key inclusion criteria

1. Critically-ill patients requiring ventilatory support and intubation, recruited from the following three ICUs: surgical, neurological, neurosurgical.
2. Expected time of ventilation > 21 days
3. Age > 18 years
4. Informed consent that the patient may be included into the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Anatomic variants or deformities of the larynx, trachea, and collum
2. Pre-existing tracheostomy
3. Pre-existing pneumonia
4. Critical trauma of the cervical vertebral column
5. Coagulopathy (thrombocytes < 60,000 per µl, prothrombin time > 40 seconds, international normalized ratio > 1.4)
6. Estimated to die within the next 24 h
7. Planned permanent tracheostomy (after laryngectomy)
8. More than 3 days of ventilation before entry into the study

Date of first enrolment
02/01/2005

Date of final enrolment
02/01/2007

Locations

Countries of recruitment
Germany

Study participating centre
Rudolf-Buchheim-Street 7
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Sponsor information

Organisation
University Hospital of Giessen (Germany)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/032nzv584

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Giessen (Germany) - Department of Anaesthesiology and Intensive Care Medicine

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