ISRCTN22208087 https://doi.org/10.1186/ISRCTN22208087

Are there differences in the clinical course of critically ill patients undergoing prolonged mechanical ventilation when performing tracheostomy early or late?

Submission date
27/02/2014

Recruitment status
No longer recruiting

Registration date
27/03/2014

Overall study status
Completed

Last Edited
03/11/2014

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A mechanical ventilator is a machine that makes it easier for patients to breathe until they are able to breathe completely on their own. The placement of a tube into the trachea (windpipe) through the mouth (tracheal intubation) is the standard procedure for patients requiring mechanical ventilation (MV). Tracheal intubation is often not well tolerated by an awake patient; is prone to potentially disastrous dislodgement; and interferes with oral care, feeding and communication. If MV is likely to be prolonged, doctors often consider converting the patient to ventilation via a tracheotomy, a surgical procedure to access the lower respiratory tract directly from the lower neck. With tracheotomy, oral care is considerably easier and it can also be possible for the patient to talk and to swallow food and liquids. It is current medical practice in intensive care units (ICUs) to perform a tracheotomy in patients undergoing prolonged MV. However, there is currently no agreement on the best time to perform the tracheotomy.
The benefits of tracheotomy include improved patient comfort, decreased risk of ventilator-associated pneumonia (VAP) and shorter duration of MV. Thus, early tracheotomy in place of longer-term oral endotracheal intubation could lead to desirable effects including shorter hospital stay, reduced costs and lower death rates (mortality). The problem with routinely performing tracheotomy early is that some patients who do not require tracheotomy undergo an unnecessary procedure. The aim of this study is to improve our understanding of the potential benefits and harms of early tracheotomy.

Who can participate?
All patients older than 18, admitted to an ICU ongoing MV for 7 or more days.

What does the study involve?
The patients were randomly allocated into two groups to undergo a tracheotomy either early (before day 8) or late (from day 14 onwards of MV). Between the third and fifth day of MV the attending physician was consulted to establish whether the anticipated duration of MV was more than 7 days. Then, he/she was asked, prior to random allocation, if he/she would accept to

perform tracheotomy in accordance with the result of the random allocation. If the attending physician agreed, the tracheotomy was carried within the specified time. In the remaining patients the attending physician would decide whether or not to perform a tracheotomy at a later date. We analyzed the differences between early and late tracheotomy and the reasons for rejecting the tracheotomy in patients with more than 7 days of mechanical ventilation.

What are the possible benefits and risks of participating?
There was no immediate direct benefit to those taking part. However, there should be benefits to future critical care patients with prolonged MV if we have more information regarding the best time to perform tracheotomy. Tracheotomy, as with any intervention, has some risks. The most common are the technical difficulties that may hinder breathing, and bleeding associated with the procedure. Our rate of complications prior to the study was low. The main risk to the participating patients was the possibility of being subjected to an unnecessary tracheotomy, in the case of being accepted by the attending physician. Therefore, the doctors assessed whether or not the patient would require a tracheotomy according to their usual clinical criteria.

Where is the study run from?
Bellvitge University Hospital (Spain).

When is the study starting and how long is it expected to run for?
The study started in January 2006 and finished in February 2009.

Who is funding the study?
Bellvitge University Hospital (Spain).

Who is the main contact?
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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
Impact of early or late tracheostomy in the clinical course of critically ill patients undergoing prolonged mechanical ventilation: a randomized clinical trial

Study objectives
It is hypothesised that early tracheostomy in patients undergoing prolonged mechanical ventilation (MV) may have benefits in relation to the duration of mechanical ventilation, ICU stay and mortality.
The null hypothesis is that there is no difference between making early or late tracheotomy. However, the main difficulty of this study is to select patients. This is due to not knowing earlier than patients will require prolonged MV. To avoid the biases that this problem can generate, we designed a consecutive selection of patients with more than 7 days of MV, to know how and why doctors, before knowing the outcome of the randomization, decided to accept or reject the protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital of Bellvitge Clinical Research Ethics Committee, 08/06/2006, ref. 150/06

Study design
Prospective single-centre randomized controlled clinical trial. Two groups with the same intervention (tracheotomy) at different time periods.

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Critically ill patients with respiratory failure of different etiologies and prolonged mechanical ventilation requirements

Interventions
The tracheotomy was performed in accepted patients according to the result of randomization: early (before day 8) or late (from day 14 onwards of MV). In the remaining patients the decision of whether or not to perform a tracheotomy at a later date rested to the attending physician. All tracheotomies were performed using the percutaneous technique.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mortality at 90 days of ICU admission

Secondary outcome measures
1. Number of days free of mechanical ventilation at 28 and 90 days
2. ICU length of stay
3. Number of days with continuous perfusion of sedatives
4. Incidence of pneumonia

These outcomes are measured using patient records.

Overall study start date
01/01/2006

Completion date
28/02/2009

Eligibility

Key inclusion criteria
Patients admitted to the intensive care unit (ICU) with:
1. Aged over 17
2. Over 2 days of mechanical ventilation and expected by attending physician to be 7 or more days of mechanical ventilation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

1452 patients

Key exclusion criteria
1. Patients already tracheotomized
2. Patients previously included in another trial
3. Technical difficulty to perform a percutaneous tracheotomy
4. Patients without limitation of life support but any of the following conditions: intracranial hypertension (ICP> 15), risk of bleeding (platelets <50000 or prothrombin time INR> 1.5), severe respiratory failure (PEEP> 10cmH20 or PO2 / FiO2 <100)
5. Patients with poor prognosis and any type of decision to limit life support measures
6. Patients requiring urgent tracheotomy on medical grounds (to improve the management of the upper airway, neurological illness, etc.)

Date of first enrolment
01/01/2006

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
Spain

Study participating centre
Servei de medicina intensiva. Hospital de Bellvitge
Barcelona
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Sponsor information

Organisation
University Hospital of Bellvitge (Hospital Universitari de Bellvitge) (Spain)

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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/00epner96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Bellvitge (Hospital Universitari de Bellvitge) (Spain)

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	29/10/2014		Yes	No