

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

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<b>Registration date</b> 27/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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?

Antonio Diaz-Prieto

adiazprietoh@bellvitgehospital.cat

## Contact information

### Type(s)

Scientific

### Contact name

Dr Antonio Diaz-Prieto

### Contact details

Servei de medicina intensiva. Hospital de Bellvitge

C/ Feixa Llarga sn. Hospitalet de Llobregat

Barcelona

Spain

08907

+34 932 60 76 46

adiazprietoh@bellvitgehospital.cat

## 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

Spain

08907

**Sponsor information****Organisation**

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

**Sponsor details**

Servei de Medicina Intensiva

C/ Feixa llarga s/n. Hospitalet de Llobregat

Barcelona

Spain

08907

+34 932 60 76 46

rmanez@bellvitgehospital.cat

**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?
<a href="#">Results article</a>	results	29/10/2014		Yes	No