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Does early removal of breathing support reduce complications in patients who have had surgery for bleeding on the brain?

Submission date
12/07/2019

Recruitment status
No longer recruiting

Registration date
28/10/2019

Overall study status
Completed

Last Edited
08/04/2020

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Patients who are having intracranial surgery (opening the skull) to treat a haematoma (bleeding on the brain) need to have a tube inserted into their airway to enable mechanical ventilation (a breathing machine) to ensure they get enough air during the operation. The patient must be sedated to some extent because the tube and mechanical ventilation is uncomfortable and potentially distressing. After surgery, patients who are still being mechanically ventilated must be cared for in the intensive care unit (ICU), where they are at higher risk of picking up an infection or suffering damage to the lungs from the mechanical ventilation. In addition, it is difficult to assess the patient's brain function when they are sedated. This trial aims to compare whether it is better to extubate (remove the breathing tube) in the operating theatre after the operation or to extubate in the ICU 8 hours after the operation and care for the patient in a post-surgical ward.

Who can participate?
Adults who need to have surgery to open their skull to remove blood that is pressing on their brain and who have not had a breathing tube inserted before the operation.

What does the study involve?
Participants were randomly allocated to one of two groups. Both groups had surgery to treat their haematoma as usual. One group were woken from anaesthesia and had the breathing tube removed in the operating theatre. Participants in the other group were taken to the ICU while still anaesthetised and had the breathing tube removed 8 hours after the end of the surgery.

What are the possible benefits and risks of participating?
Participants who were in the early extubation group might experience fewer complications of mechanical ventilation and not need to be admitted to the ICU.

Where is the study run from?
The Autonomous Univeristy of Nueva Leon (Mexico)

When is the study starting and how long is it expected to run for?
January 2014 to August 2015

Who is funding the study?
The Autonomous Univeristy of Nueva Leon (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AN14-003

Study information

Scientific Title
Fast-track extubation in patients after intracranial hematoma surgery

Acronym
FTEIHS

Study objectives

Fast track should be regarded as a routine technique in patients who meet the required criteria, so that they may be discharged faster and with fewer complications that may potentially endanger their lives or prolong their hospital stay. Deliberate delay or failed extubation increases the incidence of post-operative pneumonia, mortality and longer stays in the ICU and hospital. Another important issue, after considering the patient's life and safety first, is the economic factor. If the patient is discharged without admission to the ICU, the economic burden for the patient, the hospital or the medical insurance company is significantly reduced. This study aims to determine whether Intensive Care Unit stay and ventilator-associated complications are reduced in patients who received surgery for intracranial hematoma if they are extubated early.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2014, Comité de Ética en Investigación de la Facultad de Medicina y Hospital Universitario de la Universidad Autónoma de Nuevo León [Research Ethics Committee of the Faculty of Medicine and University Hospital of the Autonomous University of Nuevo León] (Avenida Francisco I Madero OPte s/n y Avenida Gonzalitos, Col. Mitras Centro, 64460 Monterrey, Nuevo Leon, Mexico; +52 8329 4050 ext 2870; investigacionclinica@mecuanl.com), ref: AN14-003.

Study design
Randomised controlled 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 to request a participant information sheet.

Health condition(s) or problem(s) studied
Early extubation to prevent ventilator-associated complications following intracranial hematoma surgery

Interventions
Early extubation, also known as fast track, is desirable after intracranial hematoma surgery to avoid ventilator-associated complications associated with admission to an intensive care unit (ICU). The objective of the present study was to determine whether ICU stay and ventilator-associated complications are reduced in patients who received surgery for intracranial

hematoma if they are extubated early. A total of 17 patients were randomly assigned to two groups:
In Group 1, patients were extubated early or using the fast-track method
Those in Group 2 were transferred to the ICU and extubated at 8 h post-operatively. Patients programmed to receive a cranial surgery were invited to participate into this trial. Patients from the two groups were assessed on admission to the operating room according to established standards and general anesthesia was induced with propofol (2 mg/kg) and fentanyl (2 µg/kg). Extubation time and hemodynamic stability (number of anesthetic adjustments required to maintain hemodynamic parameters within 20% of the predicted values) were assessed post-operatively.

Patients were extubated when the following criteria were fulfilled: Regular breathing, without intercostal retraction and with a respiratory rate of >8 BPM, a telespiratory CO2 pressure of 95% with an inspired oxygen fraction of 100%, presence of a swallowing reflex, hemodynamic stability (a change in baseline blood pressure of ≤15 mm Hg), and a cooperative and oriented patient able to respond to verbal instructions. Attempted fast-track extubation was performed after post-operative neurological assessment by the same responsible surgeon. The difference between the two groups was in extubation time criteria; extubation was 8 h after surgery in the conventional group, but extubation was immediately post-surgical in the fast-track group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Extubation procedure time

Secondary outcome measures
1. Blood pressure, heart rate, respiratory rate and oxygen saturation measured with an S / 5 anesthesia monitor (GE, Datex / Ohmeda) during the entire surgical procedure and the subsequent 24 h
2. Arterial pH measured every 8 h for 24 h using the Cobas B 221 blood gas analyzer (Roche)

Overall study start date
31/01/2014

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Patients about to receive open cranial surgery due to an intracranial hematoma
2. Anesthesia risk of I-III according to the American Society of Anesthesiologists (ASA)
3. Aged 18 years or over
4. No intubation prior to entering the operating room
5. Glasgow coma score of ≥8

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Total final enrolment
17

Key exclusion criteria
1. Patients with catecholamine-secreting tumors, coagulation disorders, or decompensated heart or lung disease
2. Patients with a scheduled surgery in another area of the body
3. Patients with hypovolemic shock
4. Patients whose surgeries lasted for >480 min or were accompanied by massive or uncontrollable bleeding (loss of 50% of blood volume for 3 h (~1 l/h) or >150 ml/kg of body weight or >1.5 ml/kg/min for >20 min

Date of first enrolment
31/01/2014

Date of final enrolment
30/08/2015

Locations

Countries of recruitment
Mexico

Study participating centre
Hospital Universitario “Dr Jose Eleuterio Gonzalez”
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.medicina.uanl.mx

ROR
https://ror.org/030ms0x66

Funder(s)

Funder type
University/education

Funder Name
Universidad Autónoma de Nuevo León

Alternative Name(s)
Autonomous University of Nuevo León, UANL

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

Publication and dissemination plan
This study was approved to publication by Spandidos Publication Editorial.

Intention to publish date

15/07/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	08/04/2020	Yes	No