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Comparing different types of jet ventilation during endobronchial ultrasound guided transbronchial needle aspiration

Submission date
19/11/2016

Recruitment status
No longer recruiting

Registration date
26/01/2017

Overall study status
Completed

Last Edited
27/05/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a procedure where a long tube (bronchoscope) is used to see inside the airways. Ultrasound is also used to allow doctors to take tissue samples from just outside the lungs. EBUS-TBNA is used to diagnose lung cancer. There are two common ways to access the airways: the traditional way uses a rigid bronchoscope while the newer way involves jet ventilation via a laryngeal mask, which is a less invasive artificial airway device. Until now nobody has investigated if these two types of ventilation for EBUS procedures are comparable. For both types of airway device a general anaesthetic is necessary but for rigid bronchoscopy muscle relaxants have to be used in order to avoid damage to the larynx (voice box) and the pharynx (throat). The use of muscle relaxants can result in a longer recovery time for the patients. The aim of this study is to compare these two types of jet ventilation during EBUS-TBNA.

Who can participate?
Patients at least 18 years old who are undergoing EBUS-TBNA for lung cancer staging or examination of lymph nodes

What does the study involve?
Patients are randomly allocated to be jet ventilated during EBUS-TBNA via either a laryngeal mask or a rigid bronchoscope. Treatment time varies and can last from 10 minutes to about 1 hour. The patients' recovery after anesthesia is assessed until they are moved to the normal ward.

What are the possible benefits and risks of participating?
Both ventilation methods are well established and no new methods or drugs are tested in this study.

Where is the study run from?
1. Medical University of Vienna (Austria)
2. Karl Landsteiner Privatuniversität für Gesundheitswissenschaften (Austria)

When is the study starting and how long is it expected to run for?
October 2016 to November 2018

Who is funding the study?
Medical University of Vienna (Austria)

Who is the main contact?
Dr Maria Anwar

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1638/2016

Study information

Scientific Title
A prospective randomized controlled trial examining infraglottic versus supraglottic superimposed high-frequency jet-ventilation in patients undergoing endobronchial ultrasound-guided transbronchial needle aspiration – a two-center experience

Study objectives
Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) under general anesthesia with supraglottic Jet-Ventilation using a laryngeal mask airway (LMA) with the Veres Adapter is not inferior to infraglottic Jet-Ventilation with rigid bronchoscopy regarding the outcome parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethikkommission der medizinischen Universität Wien, 10/08/2016, ref: 1638/2016
2. Ethikkommission für das Bundesland Niederösterreich, 16/09/2016, ref: GS4-EK-3/125-2016

Study design

Multicentre prospective randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
EBUS-TBNA +/- tumour biopsy

Interventions
Patients are randomised to be ventilated with either:
1. Jet ventilation via a LMA with a jet converter
2. Jet ventilation via a rigid bronchoscope (traditional method)

Treatment time varies and lasts from 10 minutes to about 1 hour. For both treatments the Aldrete score at the Post Anesthesia Care Unit (PACU) is recorded. The observation for the patient ends when they are transferred from the PACU to the normal ward.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Recovery after anesthesia, measured using the Aldrete score every 10 minutes for the first hour after admission to the PACU, every 15 minutes for the second hour, and every 30 minutes for the third hour

Key secondary outcome(s))
1. Time from anesthesia start until the end of the procedure
2. Anesthesia recovery time, defined as the time from the end of the procedure with removal of the bronchoscope until removal of the laryngeal mask
3. Diagnostic yield of EBUS-TBNA, defined as the percentage of patients for whom the procedure rendered a specific diagnosis
4. Device-related complications such as incorrect position of the LMA leading to difficulties in ventilation and gastric insufflation, difficulties to insert the rigid bronchoscope and excessive coughing that delays the procedure and requires additional medication
5. Anesthesia-related complications such as hypotension (defined as a drop in systolic blood pressure < 90 mmHg requiring intervention such as vasopressors or fluid), hypertension (an increase in mean arterial pressure > 30% from baseline longer than 5 minutes), hypoxemia (oxygen saturation < 90% for more than 1 minute), hypercarbia (PtcCO2 > 50 mmHg for more than 1 minute) and arrhythmia requiring antiarrhythmic medication
6. Severe EBUS-related complications such as bleeding, pneumothorax and mediastinitis
Measured throughout admission to the PACU

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Patients requiring EBUS-TBNA for lung cancer staging or examination of suspect mediastinal or hilar lymph nodes (at least one needle aspiration), puncture of a maximum of four lymph node stations +/- or even tumour biopsy
2. Obtained informed consent
3. At least 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Less than 18 years old
2. Pregnancy
3. Patients allergic to involved anesthetic agents
4. Patients presenting contraindications for the use of either of the two methods
5. Patients with known presence of atypical Pseudocholinesterase
6. Mediastinal mass tumors (larger than 10cm in diameter) which might compress the mediastinal vessels
7. Known severe heart failure (NYHA III+IV)
8. Patient will be transferred to the ICU after the procedure
9. Drug abuse
10. Lack of English or German language skills
11. GCS < 12
12. Severe neurologic disease that hinders postoperative assessment
13. Informed consent not obtained
14. Patients with emergency procedures
15. Patients with infections mediastinitis

Date of first enrolment
03/10/2016

Date of final enrolment
18/01/2018

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Währinger Gürtel 18-20
Vienna
Austria
1090

Study participating centre
Karl Landsteiner Privatuniversität für Gesundheitswissenschaften
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Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Medizinische Universität Wien

Alternative Name(s)
Medical University of Vienna, MediUni Wien

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
Austria

Results and Publications

Individual participant data (IPD) sharing plan
Patient data will not be published for the reasons of confidence. Only aggregated data will be published.
Data will be collected and stored in order to grant access only to authorized persons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	27/05/2020	Yes	No