

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

Submission date 19/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/05/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

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
Dr Maria Anwar

Contact details
Währinger Gürtel 18-20
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypothesis

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

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

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

03/10/2016

Overall study end date

30/11/2018

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

90 patients in two groups in two centers. Group 1 = LMA+SHFJV; Group 2 = Rigid bronchoscopy+SHFJV. 45 patients per center. Group 1 includes 30 patients and Group 2 includes 15 patients per center.

Total final enrolment

90

Participant 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

Recruitment start date

03/10/2016

Recruitment end date

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

Mitterweg 10

Krems an der Donau

Austria

3500

Sponsor information

Organisation

Medical University of Vienna

Sponsor details

Währinger Gürtel 18-20
Vienna
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1090

Sponsor type

University/education

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

Publication and dissemination plan

Results and statistical analysis will be published in a top anaesthesiological journal.

Intention to publish date

30/11/2019

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