ISRCTN54937993 https://doi.org/10.1186/ISRCTN54937993

The use of the laryngeal tube versus the endotracheal tube in out-of hospital cardiac arrest and their effects on arterial blood gas analysis

Submission date	**Recruitment status**	[X] Prospectively registered
21/06/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/09/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/12/2016	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims?
Cardiac arrest happens when the heart suddenly stops pumping blood around the body. This is a medical emergency as damage to the brain and other organs can lead to death very soon afterwards. The brain is particularly sensitive to a lack of oxygen with brain cells beginning to die after about 4 minutes. There is an ongoing discussion as to which kind of airway device used during resuscitation attempts in patients having a cardiac arrest outside of hospital (out-of hospital cardiac arrest) is most likely to result in survival of the patient and with minimal/no damage to the brain. The endotracheal tube (a tube inserted into the windpipe though the mouth or nose) is still considered the gold standard method of securing an airway and therefore delivering oxygen to the body in cases of cardiac arrest. However, there are also several supraglottic airway devices (breathing devices that sit on the larynx or voice box) available. The laryngeal tube in particular is now widely used. Some studies suggest that the laryngeal tube and other supraglottic airway devices may not be as successful as the endotracheal tube in preventing brain damage after an out-of hospital cardiac arrest. Here, we will compare the performance of the endotracheal tube and laryngeal tube during after an out-of hospital cardiac arrest. This will be done by analysing the amount of oxygen in the blood during resuscitation and also once the resuscitation is successful (that is when the patients heart begins to beat normally and they start breathing again).

Who can take part?
Adult patients with an age of over 18 years, suffering from out-of hospital cardiac arrest. Cardiac arrest should be witnessed and of presumed cardiac origin (determined by the emergency physician).

What does the study involve?
Patients suffering from an out-of hospital cardiac arrest are randomly allocated to one of two groups. Those in group 1 are treated using the laryngeal tube. Those in group 2 are treated using the endotracheal tube. Ten minutes after the airway has been secured a sample of blood from

an artery is taken to measure the amount of gas (for example oxygen) it contains. Once the patient has been admitted to hospital, another blood sample is taken to see whether there are any changes to the arterial blood gases depending on the airway device used.

What are the possible benefits and risks of participating?
We expect no extraordinary risk to the patient. The arterial puncture procedure used to collect the blood sample is performed in every patient in a critical condition when arriving the emergency department.

Where is this study run from?
Department of Emergency Medicine of the Medical University of Vienna (Austria)

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

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

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
V1.0

Study information

Scientific Title
The use of the laryngeal tube versus the endotracheal tube in out-of hospital cardiac arrest and their effects on arterial blood gas analysis: a randomized, controlled trial

Acronym
The TUTORIAL Trial

Study objectives
The use of the LT influences ventilation outcomes compared to conventional ET.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of the Medical University of Vienna, 06/06/2014, ref. 1313/2014

Study design
The study is planned in a prospective, randomized-controlled setting.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
N/A

Health condition(s) or problem(s) studied
Cardiopulmonary resuscitation, airway management

Interventions
Patients will receive either:
1. Intubation with laryngeal tube
2. Intubation with endotracheal tube
after cardiac arrest.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome is defined as arterial pCO2 measured within 10 minutes of establishing the secure airway

Secondary outcome measures
1. Any ROSC (only brief signs of circulation of less than 20 minutes, making chest compressions unnecessary)
2. Sustained ROSC (signs of circulation persist for more than 20 minutes, making chest compressions unnecessary)
3. EtCO2 continuously measured by the Lifepak 12/15 Monitor (mean value of all measurements until hospital admission, and mean value in the first 10 minutes after inclusion)
4. Quality of CPR: hands-off times
5. Time needed for airway management
6. Intubation attempts
7. Arterial blood gas analysis within 10 minutes (except apCO2, because primary outcome parameter) and on admission (pH, paCO2, pO2, lactate, BE)
8. EtCO2 on arrival
9. ΔetCO2 compared between first measured value and etCO2 on admission
10. changes values of blood gas analysis measurements (ΔpH, ΔpCO2, ΔpO2, Δlactate, ΔBE) between first measurement on-scene and first measurement at hospital admission
11. Rates of Aspiration revealed by Chest-X-ray after admission
12. 30-days survival
13. 6- months survival
14. Neurological outcome after 6 months, favorable outcome defined as CPC 1 or 2, non-favorable outcome defined as CPS >2 or deceased within 6 months.

Overall study start date
01/01/2015

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Adult patients with an age of >18 years
2. Patients with witnessed OHCA of presumed cardiac origin (determined by the emergency physician)
3. Cardiac arrest patients with ongoing chest compression cardiopulmonary resuscitation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
1400

Key exclusion criteria
1. Standardized Lund University Cardiac Arrest System (LUCAS, Physiocontrol, 22370 Lund Sweden) mechanical chest compressions not applied before randomization
2. Traumatic OHCA:
2.1. Cardiac arrest due to exsanguination, strangulation, hanging or drowning
2.2. Cardiac arrest due to presumed intracranial hemorrhage
2.3. Cardiac arrest due to respiratory failure
2.4. Patients with an Allow-natural-death- (AND) or Do-not-attempt-resuscitation (DNAR) order or patients with a terminal illness
2.5 Known or clinically apparent pregnancy
2.6. Airway device has been introduced before the emergency physician has arrived at the scene
2.7 Already established tracheostomy e.g. coniotomy
2.8. Upper airway obstruction due to a foreign body or massive pharyngeal swelling e.g. edema for example due to an allergic reaction
2.9. Ward of the state / prisoner

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Austria

Study participating centre
Department of Emergency Medicine
Vienna
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Sponsor information

Organisation
Medical University of Vienna (Austria)

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Funder(s)

Funder type
University/education

Funder Name
Medical University of Vienna (Austria)

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