

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 21/06/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 09/09/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 08/12/2016	Condition category Circulatory System	☐ Individual participant data ☐ 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 through 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?

Dr. Raphael van Tulder

mailto:raphael.van-tulder@meduniwien.ac.at

Contact information

Type(s)

Scientific

Contact name

Dr Raphael van Tulder

Contact details

Department of Emergency Medicine

Medical University of Vienna

Waehringerguertel 18-20

Vienna

Austria

AT-1090

+43 (0) 1 40400 1964

raphael.van-tulder@meduniwien.ac.at

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Austria

AT-1090

Sponsor information

Organisation

Medical University of Vienna (Austria)

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

University/education

Funder Name

Medical University of Vienna (Austria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration