

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

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<b>Registration date</b> 09/09/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/12/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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 pCO<sub>2</sub> 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. EtCO<sub>2</sub> 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 apCO<sub>2</sub>, because primary outcome parameter) and on admission (pH, paCO<sub>2</sub>, pO<sub>2</sub>, lactate, BE)
8. EtCO<sub>2</sub> on arrival
9. ΔetCO<sub>2</sub> compared between first measured value and etCO<sub>2</sub> on admission
10. changes values of blood gas analysis measurements (ΔpH, ΔpCO<sub>2</sub>, ΔpO<sub>2</sub>, 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