Laryxmask Supreme * or endotracheal tube in adults with cardiac arrest in prehospital care: a Randmised Controlled Trial

Published: 03-06-2011
Last updated: 19-03-2025

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON34188

Source
ToetsingOnline

Brief title
LMA Supreme* versus ETI in adults with cardiac arrest in prehospital care

Condition

- Cardiac arrhythmias

Synonym
cardiac arrest

Research involving
Human

Sponsors and support

Primary sponsor: Connexxion Ambulancezorg

Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: cardiac arrest, endotracheal intubation (ETI), larynxmask supreme (LMA Supreme), Randomised controlled trial (RCT)

Outcome measures

Primary outcome

Primary outcome measures

* Effectiveness will be displayed in seconds of placing (LMA Supreme*)

* The primary success rate when a secure airway was established (proven CO2

exchange)

Research question

What is the difference in safety and effectiveness between resuscitation with

LMA Supreme* and ETI performed by emergency nurses?

Secondary outcome

Secondary outcome measures

a. Aspiration

b. apparent damage to the glottis / throat

c. cuff pressure ETI too high (over 30 cm H2O)

d. inability to create a free airway (more than 3 placement attempts)

Research questions

1. What adverse events occure in ETI performed by ambulance nurses in CAZ NOG?

2. What adverse events occur when using LMA Supreme* performed by ambulance

nurses in CAZ NOG?

Study description

Background summary

Airwaymanagement and ventilation are regarded as a fundamental and essential component in the care for the critically ill patient or trauma victims in prehospital care. National and international guidelines from the Dutch Reanimation Council and the European Resuscitation Council describe endotracheaal intubation (ETI) as a primary condition for a safe airway and optimal oxygenation and ventilation. In these guidelines endotracheaal intubation (ETI) is considered as the *golden standard* for an adequate airwaymanagement and ventilation for the ambulance care in the Netherlands.
Prehospital resuscitation often takes place under far from ideal conditions. There is frequently talk of uncontrolled, stressful and sometimes chaotic conditions that put pressure on the advantages of ETI. Victims are in positions where they are difficult to access or have injuries of the face and are rarely fasted. Factors that asks a great deal in expertise of the paramedic in bag valve ventilation and intubation skills.
Several international publications in recent years show that ambulance proffessionals may not reach the level that is required to perform an adequate support of airway and ventilation. The low success rates of pre-hospital care providers indicate inadequate initial training and achieve inadequate recurrent training. To keep these skills at the desired level at least 12 intubations per annum are required while in our organization an average of 5 per annum is reached. The cost to keep the employees at the desired level is very high; minimal one day of training per annum. Complications with endotracheaal intubations by paramedics are reported in the literature are mostly on unrecognized oesophageal intubations, too high cuff pressures, unrecognized main stem bronchial intubation and prolonged and multiple attempts.
The main message that emerges from international publications is a growing burden of proof is described that ETI by paramedics is not the ideal method for airwaymanagement and even may be detrimental to the outcome of the patient. In the Dutch ambulance care there are - still - no studies being done on efficacy and safety of ETI.
The alternative to ETI in the prehospital seems to present itself with supraglottic airway devices (SAD). In the clinical setting SAD*s have shown their value as reliable, safe and effective device for some time.
Internationally, there is an increasing use of SAD's as an alternative to endotracheaal intubation in prehospital airwaymanagement. Research shows that placing a SAD by prehospital care providers has a much shorter learning curve and less training is necessary to maintain it. This allows the current training costs at least be halved.

The difference between supraglotic or endotracheaal airway management is the position of the tube and cuff. With proper endotracheaal intubation, the trachea is closed just below the vocal cords and the tip of the tube is just above the carina so that both lungs are ventilated. In supraglottic airway devices, the laryngopharynx is closed by a balloon with an opening to the larynx (laryngeal mask) or in combination with closure of the esophagus (Combitube / laryngeal tube).

The LMA is since 1990 clinically a widely accepted and respected airway device that is easy to make and very patient-friendly (less reflexes / tightness glottis). Because this is applicable in fasted patients, it was not outside the clinic. With the advent of the LMA Supreme* it is possible to place a stomach tube via an additional opening in order to improve the chances of regurgitation leveling.

Study objective

The purpose of this study is to demonstrate the added value of usingLMA Supreme* in the ambulance care in the Netherlands with CPR indigent patients. The hypothesis is that the value of using theLMA Supreme* is to be found in the safety and speed of placing the device and the positive learning curve for the paramedic.

Study design

The study is a randomized comparative trial (RCT = randomized controlled trial) between two methods to create a safe airway and effective ventilation for patients with a cardiac arrest.
In the region of North and East Gelderland all resuscitations in adults will be performed using ETI or LMA Supreme* for a period of 5 months (starting mid-February 2011). The number of patients to be included is 200 (100-100). The power calculation can be adjusted if the outcome of the pilot study clearly shows differences compared to other clinical trials.
Due to practical constraints we have decided not to collect data by an independent researcher during resuscitations but use objective data. This will be collected through the registration of vital signs (monitor Life Pack 12 and Corpuls) and a measure method what will make it possible to read the intubation time and number of attempts from a printed strip. To avoid disturbing the process of acute care we choose to have the ambulance nurse fill in an evaluation form (subjective data). If the patient is transferred to the clinic the receiving physician will also be asked to fill in an evaluation form.

Randomization
In all ambulance vehicles the emergency cases will be equipped with both devices. Randomization using numbered envelopes will be done beforehand to

decide which device will be placed. A total of 200 envelopes will be distributed on the vehicles inside the region North-East Gelderland. All relevant forms are also placed in this case. If it not possible to create a safe airway and effective airway management with the pre-identified aiway device than it is possible to use a alternative method (bailout).

Intervention

The method
For this study, the paramedic are asked to make a printout of the monitor (LP12) of cardiac resuscitations complemented by a registration form with trip number, employee number, patient data, ROSC yes or no and destination of the hospital. To determine the intubation time it is necessary that the LP12 and Corpuls Monitor will be updated with a configuration of the curve endtidal-CO2 in combination with paddles. The paramedics will be asked to start end tidal - CO2 record mode when ventilating by bagvalvemask (by placing capnometers between filter and ambu balloon and activate the printer to the monitor). After correct placement of airway device (to be checked by auscultation and registration CO2), the printer can be stopped. The installation time of the device can now be read as well as the number of attempts. To change these working methods correctly it is necessary to carry out instructions to the paramedics during work meetings and regular training days.
Immediately after resuscitation, the ambulance nurse is asked to fill out a brief questionnaire to record their experience and subjective data.
The patient*s data (name / birth date) are necessary to link the data from the digital ambulance form. The staff number is needed to question the paramedic for any gaps or ambiguities. To obtain a complete overview of all resuscitations in the study area the data from the digital patient documentation system will be requested from the quality administrator.
The procedure during the two phases (pilot / RTC) is according to the National Ambulance Protocol 7.1 except the following points:
a. Prior to placing the device the AVP will give 2 breaths with the bag valvemask.
b. Registration of CO2 will take place as soon as the AVP is ready to insert the airway device until the device is placed in the right position (this is controlled by auscultation the stomachdimple and 4 lung fields and CO2 detection).
c. In half of the research group a LMA Supreme* will be placed
d. If more than three attempts are needed a bailout will be placed (EIT or LMA Supreme* / alternative: bag valvemask)
e. After placing the airway device thorax compressions - ventilations will be continued (simultaneously)
These points are mentioned in the guidelines 2011 of the American Heart Association (AHA) and the European Resuscitation Council (ERC).

Study burden and risks

Direct therapeutic effects and risks:
Benefit:
By using an airway device which can be easily placed within the LMA Supreme* group, the expectation is that there will be a beneficial effect on the resuscitation procedure. By positioning directly above the larynx complications such as bleeding or damage are less likely to be expected.
Risks:
The risk of aspiration during the resuscitation procedure, both at ETI asLMA Supreme*, will be reduced by the placement of a nasogastric tube.
By making both techniques available as a bailout patient*s safety will improve above the current procedure (only bag valvemask as an alternative). The review organization will be asked for dispensation of ensuring subjects as required according by the WMO.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults with cardiac arrest

Exclusion criteria

Trauma patients
Patients with a trachaestoma

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2011
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Larynxmasker-supreme (LMA Supreme)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-06-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20804
Source: NTR
Title:

In other registers

Register	ID
Other	nederlands trialregister nr. 2586
CCMO	NL34236.091.10
OMON	NL-OMON20804