RCT in airwaymanagement between laryxmask supreme (LMA-S) and endotrachealetube (ETI) with adultspatient with a cardiacarrest.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20804

Source
NTR

Brief title
RCT LMA-S vs ETI

Health condition

airwaymanagment
CPR
endotracheale tube
Laryxmasker supreme
RCT

Sponsors and support

Primary sponsor: UMC St Radboud

4112 - Acute Zorgregio Oost

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Source(s) of monetary or material Support: sponser= Premier Research Group
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Intervention

Outcome measures

Primary outcome

1. Speed of placing the device;

2. Several attempts at placement;

3. Safety: CO2 exchange / air leakage.

Secondary outcome

Adverse events:

1. High cuffpressures;

2. Missing intubations;

3. Aspiration.

Study description

Background summary

Background of the study:

Airway management 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 endotracheal intubation (ETI) as a primary condition for a safe airway and optimal oxygenation and ventilation. In these guidelines endotracheal intubation (ETI) is considered as the 'golden standard' for an adequate airway management and ventilation for the ambulance care in the Netherlands.

Several international publications in recent years show that ambulance professionals 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. Complications with endotracheal 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 airway management 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). Research shows that placing a SAD by prehospital care providers has a much shorter learning curve and less training is necessary to maintain it.

With the advent of the Supreme LMA (LMA-S) it is possible to place a stomach tube via an additional opening in order to improve the chances of regurgitation leveling.

Objective of the study:

The purpose of this study is to demonstrate the added value of using LMA-S in the ambulance care in the Netherlands with CPR indigent patients. The hypothesis is that the value of using the LMA-S 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.

Pilot study:

Initially there will be a pilot to test the procedure who is specially created for this study. Twenty resuscitations will be included. This data will be compared with international publications to create a reliable power calculation.

RCT study:

In the region of North and East Gelderland all resuscitations in adults will be performed using ETI or LMA-S 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).

Direct therapeutic effects and risks:

Benefit:

By using an airway device which can be easily placed within the LMA-S 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 as LMA-S, 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.

Study objective

The purpose of this study is to demonstrate the added value of using 'LMA-S in the ambulance with CPR in the Netherlands indigent patients. The hypothesis is that the value of using the LMA-S is located in the safety and speed of placing the device and the favorable learning curve for paramedic.

Study design

The total time for this study will last for 5 months.

Intervention

Airway management:

LMA-S or ETI pleaced bij paramedic.

Contacts

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Eligibility criteria

Inclusion criteria

Adult CPR patient (>18 years old).

Exclusion criteria

1. Trauma patients;

2. Tracheastoma patients.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 34188
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2470
NTR-old	NTR2586
CCMO	NL34236.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34188

Study results

Summary results
N/A