Intubation through an I-gel laryngeal mask airway in prone position

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46187

Source
ToetsingOnline

Brief title
Intubation through an I-gel laryngeal mask airway in prone position

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)
- Nervous system, skull and spine therapeutic procedures

Synonym
Intubation in prone position

Health condition

Anesthesiologisch luchtwegmanagement

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Haaglanden Medisch Centrum

Intervention

Keyword: Intubation, Laryngeal Mask, Prone Position

Outcome measures

Primary outcome

The overall intubation success rate of VSSL use through the IILMA in subjects

in prone position.

Secondary outcome

Time for insertion of the I-gel LMA, time for intubation, glottic view obtained

by the VSSL, manoeuvres necessary for intubation, leakage of tidal volume by

ventilation through the I-gel LMA and the percentage of patients with

post-operative dysphonia and a sore throat on the recovery ward.

Study description

Background summary

Prone position ventilation is indicated in patients suffering from severe ARDS, patients undergoing spine surgery and in out-of-hospital trauma scenes. When accidental extubation occurs, there is a primary urge for ventilation since a delay in ventilation causes hypoxia with possible fatal outcome.
One method to regain the ability for ventilation is to turn the patient to the supine position and perform handbag ventilation, although this is time consuming and sometimes impossible (during spine surgery). Another method is to insert a LMA in prone position, and high success rate for ventilation are achieved. Some patients, however, need to be intubated, because of the high ventilation pressures, unfasted state or leakage of tidal volume. Inserting an endotracheal tube through the LMA is the simplest method. However, success rates are unknown and moreover, manoeuvres to increase this success rate have not been investigated previously.

Some LMA*s, such as the FastTrach and the iLMA, are especially designed for intubating through the LMA and high success rates are achieved. However, successful insertion in prone position is limited with these devices. Since the I-gel has a high success rate for ventilation in prone position, this device could be the LMA of choice. However, intubating through the I-gel has lower success rates in supine position. In prone position, this has not investigated previously. Therefore, a study with intubation through the I-gel is necessary to provide recommendations regarding this device.

One method to increase the intubation success rate is to use the VivaSight Single Lumen tube (VVSL), which has a camera at the tip of tube. This allows to alter the direction of the tube. The main disadvantage of this tube are the required resources, such as the videoscreen, the availability of the tube and the high costs compared to the simple Parker-tube. Therefore, this method is likely to be unavailable in urgent situations. In this study, the view obtained by the VVSL can be used to provide recommendations for manoeuvring the Parker endotracheal tube.

Study objective

The primary objective is to quantify the overall success rate of intubation in prone position through an I-gel LMA.

The secondary outcomes are time for insertion of the I-gel LMA, time for intubation, glottic view obtained by the VSSL, manoeuvres necessary for intubation, leakage of tidal volume by ventilation through the I-gel LMA and the percentage of patients with post-operative dysphonia and a sore throat on the recovery ward.

Study design

The study design is a prospective observational study.

Study burden and risks

The burden of this study is that participants have to endure extra pharyngeal manoeuvres (up to three) which gives a slightly higher risk of a temporary sore throat or temporary dysphonia. This manoeuvre happens under general anaesthesia. There are no other burdens (e.g. questionnaires, additional site visits or examinations).
There are no risks, since standard clinical safety measures are imbedded in this study.

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

all patients scheduled for short-lasting (< 1 hour) elective spinal surgery

Exclusion criteria

- Body mass index above 32.
- Edentulous state.
- Mouth opening of less than 3 centimeters.
- Aspiration risk due to not being fasted or diaphragm herniation.
- Professional voice usage.
- Unable to ventilate over the I-gel LMA in prone position

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 23802
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65936.098.18
OMON	NL-OMON23802