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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23802

Source
NTR

Health condition

laryngeal mask airway, intubation, prone position

Sponsors and support

Primary sponsor: Haaglanden Medical Center, The Hague
Source(s) of monetary or material Support: Haaglanden Medical Center, The Hague

Intervention

Outcome measures

Primary outcome

Succesrate of tracheal intubation

Secondary outcome

, time for insertion of the I-gel LMA (seconds), time for intubation (seconds), glottic view obtained by the VSSL (description according to modified Cormack Lehane criteria from Gaitini: grade 1: full view of the arytenoids and glottis; grade 2: epiglottis, arytenoids or glottic opening are partly visible, the structure of cords is difficult to see; grade 3: dark areas

indicating an open space; and grade 4: no part of the larynx can be identified)9, manoeuvres necessary for intubation (descriptive), leakage of tidal volume by ventilation through the I-gel LMA (millilitres) and the percentage of patients with post-operative dysphonia and a sore throat on the recovery ward.

Study description

Background summary

To be announced.

Study objective

We hypothesize a successrate lower than 70%

Study design

aug-2018: approval of METC

Jan-2018: start study
31-8-2019: Study ended prematurely for unable to achieve the primary outcome.

Intervention

The patient will receive general anesthesia in prone position and an I-gel LMA will be inserted, as is the normal clinical practice. The intervention will be an onscreen intubation of a VivaSight Single Lumen (VSSL) tube through I-gel LMA. This will consist of three attempts of intubation, all of which will be visualized by another person to limit the possibility for damage. As soon as tracheal intubation is achieved, further attempts will not be performed and the interventions for the purpose of the study will be ended.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are 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 sober or diaphragm herniation.

- Professional voice usage.

- Unable to ventilate over the I-gel LMA in prone position.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019

Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	10-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46187
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6387
NTR-old	NTR7659
CCMO	NL65936.098.18
OMON	NL-OMON46187

Study results