Oropharyngeal space in videolaryngoscopy: a randomised crossover trial measuring remaining space adjacent to the video laryngoscope blade.

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Measuring the space on the right side of the videolaryngoscope blade and the palatopharyngeal wall in a cohort of ASA I-III patients with a normal mouth opening (Mallampati I, II and III). We also want to investigate how this space differs from the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Observational invasive

Summary

ID

NL-OMON37542

Source
ToetsingOnline

Brief title
Oropharyngeal space in videolaryngoscopy.

Condition

- Procedural related injuries and complications NEC
- Upper respiratory tract disorders (excl infections)

Synonym
Phalatopharyngeal distance; distance between blade and buccal mucous membrane

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Afdelingsbudget

Intervention

Keyword: Intubation, Orofaryngeal space, Videolaryngoscopy

Outcome measures

Primary outcome

Our primary parameter is: Measuring the space on the right side of the videolaryngoscope blade and the palatopharyngeal wall in a cohort of ASA I-III patients with a normal mouth opening (Mallampati I, II and III).

Secondary outcome

Investigating how this space differs from the space that remains on the right side of the blade of the classic Macintosh laryngoscope and the palatopharyngeal wall in the same cohort of patients.

Comparing the difference in remaining space between the different videolaryngoscopes.

Registering difficulty of intubation (Cormack-Lehane score), successful intubation, use of rigid stylet, number of attempts, time until picking up endotracheal tube, epiglottic downfolding and any complication during intubation.

Study description

Background summary

Intubation using indirect videolaryngoscopy has many advantages over classic

direct laryngoscopy using the Macintosh laryngoscope. The laryngoscope blade differs between the different brands of videolaryngoscopes. The size and angle of these blade differ significantly, which may have an impact in the space available for insertion of the endotracheal tube. The space between the blade and the palatopharyngeal wall may be reduced significantly, so that there is less room in the mouth to insert an endotracheal tube. Positioning and manoeuvring of the endotracheal tube may consequently be more difficult and may traumatize the pharynx as was described in a few case reports, especially when a rigid styletted endotracheal tube was used.

Study objective

Measuring the space on the right side of the videolaryngoscope blade and the palatopharyngeal wall in a cohort of ASA I-III patients with a normal mouth opening (Mallampati I, II and III). We also want to investigate how this space differs from the space that remains on the right side of the blade of the classic Macintosh laryngoscope and the palatopharyngeal wall in the same cohort of patients.

Study design

Randomised crossover trial

Study burden and risks

The burden for patients will be minimal, since the patient will be anesthetized during the time of the study.
Probably the risk of dental trauma is slightly increased, since two laryngoscopes will be placed (instead of 1). However, videolaryngscopy has been proven to result in reduced forces on teeth, and more importantly, patients with bad or fragile dentition will be excluded. Also, other risk factors for dental trauma will be excluded as much as possible (intubation will only be performed by an experienced anesthesiologist, emergency surgery is excluded as are patients with external features predicting a difficult airway).

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

ASA I, II and III patients, aged > 18 years, who will undergo an elective surgical procedure under general anaesthesia.

Exclusion criteria

ASA IV patients undergoing emergence surgery with pre-operatively expected difficult airway, bad or fragile dentition, dental crowns and/or fixed partial denture

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2012
Enrollment:	450
Type:	Actual

Medical products/devices used

Generic name:	Videolaryngoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL38570.060.12