Epiglottic downfolding during endotracheal intubation* An alternative technique to improve glottic exposure, and facilitate intubation?

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We want to determine if epiglottic downfolding leads to a better view of the glottis and more successful intubations. We also want to investigate if this comes at the cost of more postoperative sore throat, dysphonia, dysphagia and coughing…

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

Summary

ID

NL-OMON37053

Source
ToetsingOnline

Brief title
Epiglottic downfolding

Condition

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

Synonym
compression of epiglottis, Epiglottic downfolding

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Downfolding, Epiglottis, Intubation, Videolaryngoscopy

Outcome measures

Primary outcome

Determining the Cormack and Lehane grade scored in both positions of the C-MAC®

videolaryngoscope (with and without ED).

Successful intubations

Secondary outcome

Sore throat, dysphonia, dysphagia and coughing reported by patients 2 and 24

hours postoperatively, use of a stylet, gum elastic bougie or BURP manoeuvre.

Study description

Background summary

Videolaryngoscopy with a Macintosh design videolaryngoscope is usually performed with the blade in the vallecula and the epiglottis elevated from the vocal cords indirectly, as in direct laryngoscopy. During an audit of videolaryngoscopic practice, we noticed that, in obtaining the best view, clinicians frequently and inadvertently advanced the blade into the vallecula such that the epiglottis was downfolded and elevated directly from the vocal cords. However, a better view does not necessarily lead to higher intubation success. Moreover, epiglottic downfolding could result in more complaints as dysphonia, sore throat and dysphagia.
With this study we want to investigate whether epiglottic downfolding leads to a better view of the glottis. Also, we want to investigate whether epiglottic downfolding results in more successful intubations and more complaints of dysphonia sore throat, dysphagia and coughing.

Study objective

We want to determine if epiglottic downfolding leads to a better view of the glottis and more successful intubations. We also want to investigate if this comes at the cost of more postoperative sore throat, dysphonia, dysphagia and coughing complaints of patients.

Study design

Randomized controlled

Study burden and risks

Risks and burden are negligible, patients will be anaesthetised in a conventional matter and apart from the study protocol, intubation would still be mandatory. When participating in this study, patients will be intubated only once (as when not participating). The difference will be the achievement of epiglottic downfolding. We believe this not a harmful procedure, which occurs often without the anaesthesiologist noticing. The fact that epiglottic downfolding will be visible makes it possible to correct the position of the epiglottis once the endotracheal tube has been placed.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Informed patient consent
ASA I-III
Age > 18 years
Elective surgery, other than head and/or neck surgery
Elective surgery, < 1 hour in supine position
Pre-operative Mallampati I-II-III

Exclusion criteria

No informed patient consent
ASA IV
Age < 18 years
Emergency surgery, surgery of head and/of neck
Surgery > 1 hour in other than supine position
Preoperative complaints of sore throat, dysphagia, dysphonia and coughing
Locoregional anaesthesia
Pre-operative Mallampati IV
Known difficult airway
Bad dentition
Dental crowns and/or fixed partial denture
Risk of aspiration (fasted < 6 hours, gastro-oesophageal reflux)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2013
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	Videolaryngoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-09-2012
Application type:	First submission
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	NL40875.060.12