

Comparison of the applied forces to the maxillary incisors during laryngoscopy: Evaluation of the classical McIntosh (direct vision of vocal cords) and the video-laryngoscopy (indirect vision of the vocal cords).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON31423

Source

ToetsingOnline

Brief title

Forces during laryngoscopy

Condition

- Respiratory tract therapeutic procedures

Synonym

nvt

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anesthesia, Forces, laryngoscopy, Maxillary incisors

Outcome measures

Primary outcome

The main study parameters are force on the maxillary incisors and the time taken for laryngoscopy, as previously alluded.

Secondary outcome

The secondary study parameters are the experience of the anaesthesiologist and the difficulty of intubation (to relate a scale of difficulty of intubation to the primary parameters).

Study description

Background summary

Although the use of modern laryngoscopes is successfully in the majority of patients, in some patients visualization of the tracheal entrance is not possible. The exerted force, needed to provide an insight on the tracheal entrance during laryngoscopy may vary, but there are cases where these forces cause damage to structures like the maxillary incisors. In order to prevent this damage and to improve the laryngoscopic procedure, a new laryngoscope is designed. The Video Macintosh Laryngoscope is a relatively new intubation device with video module imaging technology embedded within the blade. The image from the video module is displayed on an external monitor. This technology makes it possible to perform a visually controlled intubation. However, the exerted forces during laryngoscopy applied by this video-laryngoscope are not studied yet. The aim of this study is to measure and describe the eventually difference of magnitude of forces on the maxillary

incisors, applied by the video-laryngoscope in comparison with a standard Macintosh laryngoscope. The collected data will be analyzed for a significant difference between both laryngoscopes.

Study objective

The primary objective is to measure the forces on the maxillary incisors applied by two different laryngoscopes during endotracheal intubation. With sensors integrated with the blade of the laryngoscopes, applied forces are being measured. We hypothesize that the videolaryngoscope exert less force than the standard laryngoscope.

Study design

This study is a non-invasive study where forces are being measured.

Study burden and risks

For the participants, there are negligible risks associated with the study. Laryngoscopy itself brings minimal risk but this study will not increase that risk. This study will not require other conditions as standard laryngoscopy.

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

18 years old or older, ASA I and II

Exclusion criteria

when tracheotomy is necessary

patients under 18 years of age

patients not ASA I or II

patients requiring non-standard blade sizes other than three or four

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	09-05-2007
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	NL17266.060.07