ISRCTN28037056 https://doi.org/10.1186/ISRCTN28037056

Videolaryngoscopy results in less forces exerted on the upper teeth during intubation compared to direct laryngoscopy

Submission date 26/09/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/10/2010	**Overall study status** Completed	
Last Edited 29/10/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Videolaryngoscopy results in less forces exerted on the upper teeth during intubation compared to direct laryngoscopy: a single centre randomised controlled cross-over study

Study objectives
Three videolaryngoscopes (McGrath, C-Mac and Glidescope Cobalt) exert reduced forces on both upper and lower teeth, compared to a classic Macintosh laryngoscope blade.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Catharina Hospital Eindhoven (Netherlands)

Study design
Single centre randomised controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Intubation technique

Interventions
After three minutes of oxygen administration via facemask, intravenous (iv) induction of general anesthesia (1 µg/kg fentanyl, 3 mg/kg propofol and 0.7 mg/kg rocuronium) the following interventions will be performed:

Direct laryngoscopy:
1. Macintosh classic laryngoscope (blade III)

Indirect laryngoscopy with one of three indirect videolaryngoscopes:
1. McGrath (Aircraft Medical, Edinburgh, UK)
2. C-MAC (Karl Storz, Tuttlingen, Germany)
3. Glidescope Cobalt (Verathon, Bothell, WA, USA)

Intubation: endotracheal tube 7.5 mm (female) or 8.0 mm (male). After two unsuccessful attempts a stylet will be inserted into the endotracheal tube.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Differences between direct and indirect laryngoscopies with respect to the frequency with which forces are applied on the upper and lower teeth. The measurement of forces will be performed with Flexiforce (r) sensors (A201-25, Tekscan, MA) fixed to the blade of the laryngoscope at the possible area of contact with the teeth.

Secondary outcome measures
For the cases in which forces are being applied, differs the magnitude of forces between the laryngoscopes?

Overall study start date
01/11/2010

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) grade I - II
2. Normal airway
3. Undergoing a surgical intervention for which endotracheal intubation is indicated
4. Aged 18 years or above, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Younger than 18 years
2. Patients requiring more than blade size III of laryngoscope
3. Patients with pre-operative predictors of a difficult airway (Mallampati score IV, thyromental

distance less than 65 mm, interincisor/interdental distance less than 35 mm)
4. Patients with inadequate neck movement
5. ASA III - IV
6. Patients requiring surgery of the face and throat

Date of first enrolment
01/11/2010

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
P. Debyelaan 25
Maastricht
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6229 HX

Sponsor information

Organisation
Catharina Hospital Eindhoven (Netherlands)

Sponsor details
Department of Anesthesiology, ICU and Pain Therapy
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qavk531

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Catharina Hospital Eindhoven (Netherlands) - Department of Anesthesiology, ICU and Pain Therapy

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration