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Evaluation of Truflex™ Flexible Stylet as an intubation guide with the D-blade of C-Mac videolaryngoScope during elective tracheal intubation

Submission date
02/02/2013

Recruitment status
No longer recruiting

Registration date
12/02/2013

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients who are very sick in the intensive care unit (ICU) or those undergoing general anesthesia for surgery require their breathing passage (trachea) to be connected to the ventilator by a tube called the endotracheal tube (ETT). To help locate the glottis, which is the opening of the trachea inside the patients mouth, a special device called the videolaryngoscope is used. With the help of this device, the image of the glottis can be visualized from the tip of the videolaryngoscope blade onto a viewing screen outside. Although videolaryngoscopes provide excellent visualization of the glottis, they often pose difficulty in inserting the ETT into the trachea via the glottis. This is mainly due to the fact that the blades of these devices are highly angulated while the natural curvature of the ETT does not match this angulation and hence fails to be directed towards the visualized glottis. To overcome this, a rigid malleable stylet is placed inside the ETT to give it a desired angulated shape matching that of the videolaryngoscope blade. Unfortunately, the curvature of the styleted ETT cannot be tailor-made to suit individual patients (the glottis position may slightly differ from one patient to the next). This often leads to more than one attempt at inserting the ETT into the glottis: during each attempt the styleted ETT is taken out of the patients mouth and its curvature increased or decreased. This takes time and may lead to greater chances of injury to the patients mouth cavity and increased heart rate and blood pressure.
To avoid the handicap of the rigid stylet, we aim to use a flexible stylet inside the ETT called the TruflexTm which will make it easier to use the tip of the ETT by pressing on a lever near the operator end of the stylet. We think that this combination of videolaryngoscope and TruflexTm will not only help inserting the ETT into the patients trachea but will also reduce time and the incidence of injuries and changes in heart rate and blood pressure.

Who can participate?
All patients coming for elective surgical procedures under general anesthesia needing tracheal intubation can participate in this trial after expressing their verbal consent.

What does the study involve?
Participants will be randomly divided into 2 groups. All patients shall be intubated with the aid of same type of stylet within the ETT, either TruflexTm or PortexTm.

What are the possible benefits and risks of participating?
The outcome of this trial shall benefit patients whose tracheas are to be intubated using videolaryngoscope. There are no added risks that can be attributed to the intervention.

Where is the study run from?
The study shall be run at two different centers: Department of Anesthesia & ICU, Khoula Hospital, Muscat, Sultanate of Oman and Department of Medicine, Jawahar Lal Nehru Medical College, Aligarh, India. The lead centre will be the Department of Anesthesia & ICU, Khoula Hospital, Muscat, Sultanate of Oman.

When is the study starting and how long is it expected to run for?
The study shall commence once we get the approval of the Ethical Issues Committee of the hospital. This generally takes 4-6 weeks. We expect to commence data collection from end of March 2013. We expect that the initial study should be completed within 4-6 weeks. However, the larger study is expected to run for about 6-7 months.

Who is funding the study?
The two researchers (Rashid M Khan & Naresh Kaul from Khoula Hospital, Oman) have personally purchased the TruflexTm flexible stylet. The other devices needed for the study are freely available in the operation theatres of both institutions and needs no funding.

Who is the main contact?
Dr. Naresh Kaul, Senior Consultant
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Contact information

Type(s)
Scientific

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Dr Naresh Kaul

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Additional identifiers

Protocol serial number
U1111-1139-2029

Study information

Scientific Title
Assessment of Truflex™ Flexible Stylet versus conventional rigid Portex™ stylet as an intubation guide with the D-blade of C-Mac videolaryngoScope during elective tracheal intubation

Acronym
TruScope

Study objectives
Endotracheal intubation with the D-blade of C-Mac videolaryngoscope using Truflex™ Flexible Stylet as an intubation guide is easier than using connventional rigid Portex™ stylet as an intubation guide during elective tracheal intubation.

On 24/09/2013, India was removed from the countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical issues committee, Khoula Hospital, Muscat, Sultanate of Oman, 2nd March 2013, MOH/KH /EIC/2/2013

Primary study design
Interventional

Study design
Interventional open-label parallel randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients undergoing elective surgical procedure under general anesthesia needing tracheal intubation

Interventions
Endotracheal Intubation with C-Macs D- blade videolaryngoscope by an experienced anesthesiologist using either of the following two intubation guides.

Study Group A: A well lubricated conventional rigid stylet (Portex) will be used to shape the ETT according to the curvature of thevideolaryngoscope blade. This preshaped ETT will be guided into the trachea after obtaining an adequate view of the glottis of an anesthetized and fully relaxed patient using C-Macs D- blade videolaryngoscope by an experienced anesthesiologist.

Study Group B. A well lubricated Truflex flexible stylet will be used in place of the rigid stylet to change the curvature of the ETT as per need to negotiate into the glottis of an optimally anesthetized and relaxed patient using C-Macs D- blade videolaryngoscope by an experienced anesthesiologist.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 24/09/2013:
1. Successful or failed intubation at the first attempt
2. Total Intubation Time - This shall include:
2.1. Glotticoscopy time (From introduction of the videolaryngoscope blade between the teeth to the best laryngeal view)
2.2. ETT negotiation time (From receiving the styleted ETT in laryngoscopists hand to passage of black line just beyond the vocal cord.
3. Intubation Difficulty Score

Previous primary outcome measures:
1. Successful or failed tracheal intubation
2. Total Intubation Time - This shall include:
2.1. Glotticoscopy time (From introduction of the videolaryngoscope blade between the teeth to the best laryngeal view)
2.2. ETT negotiation time (From receiving the styleted ETT in laryngoscopists hand to passage of black line just beyond the vocal cord.
3. Intubation Difficulty Score

Key secondary outcome(s)
1. Intubation attempts - maximum three attempts, after which the technique will be considered as failure. An attempt shall be counted if the laryngoscope or the ETT needs to be removed for re-oxygenation (drop in oxygen saturation by 5%) or for reshaping of the ETT.
2. Glotticoscopy time & ETT negotiation time as described in primary outcome measure above
3. Overall user satisfaction (Scale 1-10): 1-3=Poor, 4-6=Fair, 7-10=Good)
4. Cormack & Lehannes grading

Completion date
15/10/2013

Eligibility

Key inclusion criteria
1. Patient has been informed of the investigational nature of this study and has given verbal informed consent in accordance with Hospital Ethical Committee guidelines.
2. Males or females ≥ 18 - 60 years of age
3. American Society of Anesthesiologists grade I and II patients
4. Elective surgical procedure under general anesthesia needing tracheal intubation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant female
2. Known allergies to either study devices or its components
3. Known bleeding/coagulation disorder
4. Immobilized cervical spine
5. Any pathologies of the mouth, pharynx or larynx
6. Previous ENT surgeries
7. Known malignancies prior to randomisation
8. Chronic kidney disease, chronic liver disease or heart failure

Date of first enrolment
15/03/2013

Date of final enrolment
15/10/2013

Locations

Countries of recruitment
Oman

Study participating centre
Senior Consultant
Muscat
Oman
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Sponsor information

Organisation
Ministry of Health (Oman)

ROR
https://ror.org/0362za439

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded (Oman)

Funder Name
Khoula Hospital (Oman) - Research grants from of the Department of Anesthesia & ICU

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2015	18/01/2019	Yes	No
Protocol article	protocol	16/09/2013		Yes	No