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Comparison between two techniques of endotracheal intubation on blood pressure and heart rate in patient undergoing general anesthesia for elective surgery

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
19/03/2018

Overall study status
Completed

Last Edited
10/09/2018

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Direct laryngoscopy (DL) is a procedure using a small flexible tube with a light and video camera at one end (laryngoscope) which is inserted through the mouth to examine the larynx (voicebox) during tracheal intubation (insertion of a plastic tube into the airway during surgery under general anesthesia. It can cause a high heart rate (tachycardia) and high blood pressure which could be fatal in a patient with a brain injury. Bonfils fiberscope and C-MAC videolaryngoscope are two methods of laryngoscopy associated with more stable blood flow variables (hemodynamics) compared to DL. The aim of this study is to determine the hemodynamic effects of Bonfils compared to C-MAC in patients undergoing elective surgery.

Who can participate?
Adults aged 18 – 60 years old undergoing elective surgery

What does the study involve?
Participants are randomly assigned to one of two groups. Those in the first group receive intubation with Bonfils fiberscope, and those in the second group receive C-MAC videolaryngoscopy, whilst under general anaesthetic. Heart rate and blood pressure are recorded throughout the surgery.

What are the possible benefits and risks of participating?
There are no additional benefits or risks associated with these interventions as they are both frequently used in clinical practice.

Where is the study run from?
Centre Hospitalier Universitaire de Sherbrooke (Canada)

When is the study starting and how long is it expected to run for?
October 2013 to January 2016

Who is funding the study?
University of Sherbrooke (Canada)

Who is the main contact?
Dr Frederick D’Aragon (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Frederick D'Aragon

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
None

Study information

Scientific Title
Hemodynamic responses to tracheal intubation with Bonfils compared to C-MAC videolaryngoscope: a randomized trial

Study objectives
Intubation using Bonfils would increase mean arterial pressure and heart rate less than with C-MAC

Ethics approval required
Old ethics approval format

Ethics approval(s)
Étienne Le Bel Clinical research Centre (Centre de recherche clinique Étienne-Le-Bel), 18/08/2014, ref:14-111

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
General anesthesia for elective surgery

Interventions
Participants are randomly assigned in a 1:1 ratio through a computer generated sequence, to receive intubation with Bonfils or C-MAC. After a standardized induction, intubation is done via the retromolar approach (Bonfils group) or via videolaryngoscopy (C-MAC group). Participants have heart rate (HR) and arterial blood pressure (systolic, diastolic and mean arterial blood pressure [MAP]) measured at induction and at every minute during the five minutes post intubation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Hemodynamic response to intubation is measured using heart rate (HR) and arterial blood pressure (systolic, diastolic and mean arterial blood pressure [MAP]) at induction and every minute for the first five minutes post intubation.

Secondary outcome measures
Duration of intubation (defined as introduction of Bonfils or C-MAC in the oral cavity until confirmation of proper positioning of the endotracheal tube) is measured by a positive capnography reading.

Overall study start date
01/10/2013

Completion date
25/01/2016

Eligibility

Key inclusion criteria
1. Elective surgery
2. Classified as American Society of Anesthesia (ASA) 1 or 2
2. Aged 18-60 years old.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patient refusal
2. Known Cormack-Lehane grade ≥ 2
3. Known Mallampati > 2
4. Known Patil < 4 cm
5. Mouth opening < 3 cm
6. Active smoking
7. Chronic hypertension.

Date of first enrolment
01/09/2014

Date of final enrolment
23/08/2015

Locations

Countries of recruitment
Canada

Study participating centre
Centre Hospitalier Universitaire de Sherbrooke
300, 12th Avenue North

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Sponsor information

Organisation
Department of Anesthesiology, Faculty of Medicine and Health Sciences

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Sponsor type
University/education

ROR
https://ror.org/00kybxq39

Funder(s)

Funder type
University/education

Funder Name
Université de Sherbrooke

Alternative Name(s)
University of Sherbrooke, UdeS, UDS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
25/01/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Registry of Open Access Repositories, weblink: http://roar.eprints.org/cgi/users/home?screen=Items). Type of data available: non sensitive data at the patient level, anonymised, and available after 3 months. To request access please contact the Frederick D'Aragon (study PI).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/03/2018	26/03/2018	No	No
Results article	results	07/09/2018		Yes	No