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Comparison of the semi-flexible fiberscope SensaScope® and the rigid Bonfils® for intubation in simulated difficult airway

Submission date 28/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2011	**Overall study status** Completed	
Last Edited 20/10/2020	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Endotracheal intubation is a medical procedure that is performed when a patient cannot breathe on their own. A tube is placed into their windpipe through their mouth or nose. Bonfils and SensaScope are two devices used in endotracheal intubation that both have a good success rate in normal conditions. However, their success rate in difficult intubation conditions is not known. The aim of this study is to compare those two devices when used on patients scheduled for elective surgery who require general anesthestic with endotracheal intubation.

Who can participate?
Patients aged over 18 who choose to have surgery (elective surgery) requiring general anesthestic and endotracheal intubation

What does the study involve?
Participants wear a stiff collar around their neck that mimics difficult intubation conditions and limits mouth opening. Participants are randomly allocated to be intubated using either the Bonfils or the SensaScope. Intubation success rate, time necessary for intubation and side effects are assessed. The collar is removed after intubation or in case of failure of the devices.

What are the possible benefits and risks of participating?
There are no benefits and no specific risks involved. No more side effects are expected than with normal endotracheal intubation. If the device fails, the stiff collar can be removed.

Where is the study run from?
University Hospital Inselspital Bern (Switzerland)

When is the study starting and how long is it expected to run for?
June 2011 to July 2012

Who is funding the study?
University Hospital Inselspital Bern (Switzerland)

Who is the main contact?
Prof. Robert Greif

Contact information

Type(s)
Scientific

Contact name
Prof Robert Greif

Contact details
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Additional identifiers

Protocol serial number
KEK 247/09

Study information

Scientific Title
Comparison of the semi-flexible fiberscope SensaScope® and the rigid Bonfils® for intubation in simulated difficult airway: a randomized controlled trial

Acronym
BoSS

Study objectives
The Bonfils®, compared to the SensaScope®, has a 15% higher failure rate of tracheal intubation in this simulated difficult airway scenario.

H0 = Success rate Bonfils® success rate SensaScope® ≤ 15% (difference).
Alternative hypothesis H1 = Success rate Bonfils® success rate SensaScope® >15% difference.

Additionally, learning curves for both devices will be established.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bern Cantonal Ethics Commission [Kantonale Ethikkommission Bern], 22/02/2010, ref: KEK 247 /09

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Perioperative airway management

Interventions
The patients will receive a stiff collar around their neck befor intubation to stabilize the neck and reduce mouth opening (simulation of a difficult airway). Patients will be randomly assigned to the either being intubated with the Bonfils® or with the SensaScope®.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Intubation success rate

Key secondary outcome(s)
1. Time necessary for intubation
2. Side effects

Completion date
01/07/2012

Eligibility

Key inclusion criteria
1. 18 years of age
2. Elective surgery in general anesthesia requiring endotracheal intubation
3. Informed consent given

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
740

Key exclusion criteria
1. High risk of aspiration (non-fasted, massive gastroesophageal reflux disease)
2. Known difficult mask ventilation
3. Mouth opening < 20mm
4. Patients not speaking German or French
5. Refusing to participate

Date of first enrolment
01/06/2011

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Inselspital
Bern
Switzerland
CH-3011

Sponsor information

Organisation
University of Bern (Switzerland)

ROR
https://ror.org/02k7v4d05

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Inselspital Bern (Switzerland)

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	16/10/2020	20/10/2020	Yes	No