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

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

## Contact information

#### Type(s)

Scientific

#### Contact name

Prof Robert Greif

#### Contact details

Department of Anesthesiology and Pain Therapy Murtenstrasse Inselspital Bern Switzerland CH-3011

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### 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

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 measure

Intubation success rate

## Secondary outcome measures

- 1. Time necessary for intubation
- 2. Side effects

#### Overall study start date

01/06/2011

#### 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** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

800

#### 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)

#### Sponsor details

Department of Anesthesiology and Pain Therapy Murtenstrasse Inselspital Bern Switzerland CH-3011

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robert.greif@insel.ch

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.insel.ch/

#### **ROR**

https://ror.org/02k7v4d05

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

University Hospital Inselspital Bern (Switzerland)

# **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

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/10/2020	20/10/2020	Yes	No