

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

<b>Submission date</b> 28/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/10/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## 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 anesthetic with endotracheal intubation.

### Who can participate?

Patients aged over 18 who choose to have surgery (elective surgery) requiring general anesthetic 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**  
Department of Anesthesiology and Pain Therapy  
Murtenstrasse  
Inselspital  
Bern  
Switzerland  
CH-3011

## 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 before intubation to stabilize the neck and reduce mouth opening (simulation of a difficult airway). Patients will be randomly assigned to 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?
<a href="#">Results article</a>	results	16/10/2020	20/10/2020	Yes	No