# "ORSIM"

## A prospective, randomised controlled study

**(Version 1.0 February 14th, 2018)**

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**LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS**

| | |
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| **ABR** | **General Assessment and Registration form (ABR form), the application form that is required for submission to the accredited Ethics Committee; in Dutch: Algemeen Beoordelings- en Registratieformulier (ABR-formulier)** |
| **AMC** | **Academical Medical Centre (Dutch: Academisch Medisch Centrum)** |
| **AVG** | **Algemene Verordening Gegevensbescherming** |
| **DPIA** | **Data protection impact assessment** |
| **DSMB** | **Data Safety Monitoring Board** |
| **GCP** | **Good Clinical Practice** |
| **GDPR** | **General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)** |
| **aFOI** | **Awake Fiberoptic Intubation** |
| **IC** | **Informed Consent** |
| **IQR** | **Interquartile Range** |
| **METC** | **Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)** |
| **N.a.** | **Not applicable** |

| | |
|---|---|
| **NVA** | **National Society of Anaesthesia** |
| **ORSIM®** | **Bronchoscopy Simulator** |
| **SD** | **Standard Deviation** |
| **Sponsor** | **The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor but referred to as a subsidising party.** |
| **WMO** | **Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen** |

## 1. INTRODUCTION AND RATIONALE

The difficult airway remains challenging, not only for novices, but also for experienced anaesthetists. Awake fibreoptic intubation (aFOI) is an advanced technique for airway management and is frequently performed in patients with expected difficult airways. aFOI is still considered the standard procedure for patients with an expected difficult airway.[1, 2] However, exposure to aFOI has been shown to decrease over the last years, partly due to the availability of supraglottic airway devices and video laryngoscopy.[3, 4] In addition, the increased focus on patient safety along with the increased focus on the level of competency, allowing only competent caregivers to perform FOI, also contributes to this decline.[5-7] Previous studies have suggested that each novice needs an average of twenty to twenty-five procedures to become competent in successfully and safely performing FOI.[6, 8] However, aFOI are not carried out daily, making it difficult for residents to gain sufficient practice in obtaining the necessary FOI skills. Therefore, in order to ensure that anaesthetists and anaesthesia residents gain sufficient practice, as well as maintain their level of proficiency with aFOI, new educational strategies are necessary.

The rapid advancement in computer science and bio-engineering also facilitates new educational methods to train the respective situations.[9, 10] Several studies have shown that practice on normal airways with “low fidelity” simulators and virtual reality leads to improved FOI skills.[6, 11-14] However, until recently, it was not possible to train on different abnormal airways, as there were no simulators to mimic the great variety of the abnormal airway. The ORSIM® bronchoscopy simulator (ORSIM® Airway Simulation Ltd., Auckland, New Zealand) is a combined high-fidelity and virtual reality simulation tool consisting of three components: a replica bronchoscope, an interface and a laptop. These three components interact with software to create a high-fidelity virtual reality simulation of normal and difficult airways. By advancing the replica bronchoscope through the interface, the hand motion is tracked, which enables the translation of hand and scope movements into

simulated endoscopic views on the laptop screen. Contrary to previous simulators, this program also offers a variety of difficult airway scenarios along with information and clinical treatment options (e.g., supplementing oxygen and suctioning). This bronchoscopy simulator therefore facilitates practicing the technical skills of normal and difficult FOI. In 2016, Baker and colleagues showed that this simulator could be used to differentiate between various levels of competency with FOI.[7]

It is unknown, however, whether repeated training with the bronchoscopy simulator also improves FOI skills in practice. We hypothesised that regular training with a bronchoscopy simulator would improve FOI skills, as measured by the time to successful visualisation or reaching the carina during FOI. We additionally set out to examine the relationship between participants' level of FOI expertise and time to successful reaching the carina during FOI.

## **2**. **OBJECTIVES**

The primary objective of this randomised controlled trial is; if regular training with a bronchoscopy simulator would improve FOI skills, as measured by the time to successful visualisation or reaching the carina during FOI.

Secondary objectives include:

- Other outcome variables, defined as the time from introduction of the fiberscope to reaching the carina with a maximum time limit of 10 minutes we:
  - Goals reached – predetermined goals such as vocal cords or carina, scored as an absolute value
  - Total distance in millimetres, defined as all movements from introduction into the oral or nasal cavity, until reaching the carina or at ten minutes (this included all movements of the scope within the body)
  - Total rotation in degrees, defined as the cumulative number of degrees turned, with either the tip or the whole fiberscope

  - Direction changes measured in absolute numbers, defined as every change in direction (deeper, shallower, left, right, diagonal)
  - Maximum speed in mm/second, measured during insertion of the fiberscope until reaching the carina or to 10 minutes after start
  - Tissue collisions in absolute numbers
  - Tissue collisions impact in mm/second, defined as (collision-speed X collision-angle)/ 1000
- We examine the relationship between participants' level of FOI expertise and time to successful reaching the carina during FOI.

**3. STUDY DESIGN**

This research project is designed as a single-centre, prospective randomised controlled study, that will be conducted between 1st of March 2018 and the 31st of July 2019 in the Netherlands. The study will be conducted among volunteers consisting of anaesthetic nurses, anaesthesia residents and consulted anaesthetist connected to the anaesthesia department of the Amsterdam University Medical centre, a tertiary teaching hospital.

Participants were randomly assigned to one of two groups; the intervention group received FOI skill training with the bronchoscopy simulator in the use and dexterity of the fiberscope for ten minutes every six weeks; the control group received no additional training. Participants were evaluated by performing three simulated ‘difficult airway’ cases on the bronchoscopy simulator six months and twelve months after the baseline measurement. At the same time, participants are asked to complete one short questionnaire with questions that are not burdensome and do not harm the participants’ integrity.

After review of the trial protocol, the Medical Ethics review Committee of the AMC confirmed that the study did not fall under the Medical Research Involving Human Subjects Act (W18_068#18.008).

## 4. STUDY POPULATION

### 4.a Population (base)

The study population will consist of anaesthetic nurses (novice), anaesthesia residents (intermediate) and consulted anaesthetist (experts) connected to the anaesthesia department of the Amsterdam University Medical centre, a tertiary teaching hospital. Who will be approached to participate on a voluntary basis.

### 4.b Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Participants have to be members of the anaesthesia department of the Amsterdam University Medical centre.
- Participants have to agree to terms described in informed consent.
- Participants have to be able to understand and respond in the Dutch language.

### 4.c Exclusion criteria

The only exclusion criterion was previous experience with the ORSIM® simulator.

### 4.d Sample size calculation

The sample size calculation was based on literature. Ost and colleagues demonstrated that an improvement in speed of 50% can be expected with training.[6] According to Baker and colleagues,[7] this improvement in speed is the smallest for experts, who have an objective scenario time of 116 seconds (SD 17) without training. Theoretically, their scenario time would decrease (improvement of performance) to 58 seconds with training.

To be able to detect an improvement in scenario time of at least 10% with training (i.e. an improvement from 116 seconds to 99 seconds), we calculated a sample size of

33 participants per group, with a total number of 66 participants. To correct for potential drop outs we aimed to include 72 participants.

## 5. METHODS

### 5.1 Data collection

Anaesthetic nurses (novice), anaesthesia residents (intermediate) and consulted anaesthetist (experts) connected to the anaesthesia department of the Amsterdam University Medical centre, a tertiary teaching hospital, will be asked to participate on a voluntary basis, in this prospective data collection. They will be informed about the data collection and if willing to participate, they will sign a consent or no- objection for the re-use of their care data.

We aimed to include 36 participants per group (control versus intervention), with three equal sub-groups of twelve participants per subgroup, stratified for level of expertise. Participants were randomly assigned to one of two groups; the intervention group received FOI skill training with the bronchoscopy simulator in the use and dexterity of the fiberscope for ten minutes every six weeks; the control group received no additional training. Participants were evaluated by performing three simulated 'difficult airway' cases on the bronchoscopy simulator six months and twelve months after the baseline measurement. The measurements took place in a simulation laboratory in the presence of a single observer, who assisted with the study set-up and timing of the cases. A reminder will be sent to them before every practice and/or measurement, until they complete it.

### 5.2 Outcome parameters

The primary outcome is if regular training with a bronchoscopy simulator would improve FOI skills, as measured by the time to successful visualisation or reaching the carina during FOI.

Secondary outcomes include other variables measured by the ORSIM simulator and the relationship between participants' level of aFOI expertise and time to successful reaching the carina during aFOI.

## 6. RISKS ASSOCIATED WITH THE DATA COLLECTION

Study related risk assessment: The burden of participation is considered low. No risks of participation are to be expected. Participating volunteers will not be subjected to any additional risk as compared to non-participating medical residents and supervisors.
Study related benefits: Participants will be able to gain additional practice in aFOI, especially in the difficult airway cases.

## 7. DATA MANAGEMENT AND STATISTICAL ANALYSIS

All study data will be stored in the ORSIM® bronchoscopy simulator and then transferred to a Good Clinical Practice compliant database (Castor EDC) [15]. Quality of the data will be ensured by double data entry and all analyses will be performed with IBM SPSS Statistics for Windows, version 26.0 (IBM Corp).
A p-value < 0.05 will be considered statistically significant. Data will be presented as mean with standard deviation (SD) or median with inter quartile range (IQR), depending on distribution of the data. Categorical data will be expressed as percentages and counts.
To compare the time to successful reaching the carina between the control and intervention group, we will be using a Mann-Whitney U test and will be performing a Kaplan Meier analysis. We also will be using the Kaplan Meier analysis to assess the effect of training on the secondary outcomes (e.g., rotation, distance, direction changes, speed, impact, tissue collisions). For other secondary outcomes such as participants' estimation of own skills, stress level and degree of training in performing a FOI, we will be using a Wilcoxon signed rank test to assess between-group differences.

## 8. ETHICAL CONSIDERATIONS

The study will be conducted according to the principles of the Declaration of Helsinki. Participating volunteers will need to provide informed consent before participation in the study can occur. Informed consent is ensured by dependency-measures implemented in the Castor-created survey, which disable the option to continue to fill in the questionaire without provident of informed consent.

All information and data concerning the participants in this data collection will be considered confidential and handled in compliance with the AVG requirements. Participants data will be collected and registered using a code, which is not based on any personal characteristics. All coded data collected under this protocol, will be stored according to local regulations in closed cabinets, in code protected offices. Only members of the research team will have access to the collected data. Data will be stored for 5 years and archived according to local standard operating procedures.

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