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# Validation of the ORSIM simulator as an assessment method of anesthetists skills at placing a breathing tube in patients (intubation)

**Submission date**
01/07/2020

**Recruitment status**
No longer recruiting

**Registration date**
07/07/2020

**Overall study status**
Completed

**Last Edited**
06/08/2024

**Condition category**
Respiratory

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

## Plain English summary of protocol

Background and study aims
Gaining experience in awake fiberoptic intubation is difficult due to a lack of adequate training opportunities on difficult airways. The ORSIM is a virtual reality bronchoscopy simulator which contains multiple difficult airways and is being developed to address this problem.
The aim of our study is to evaluate if the ORSIM is a valid method to test anaesthesiologists fiberoptic intubation skills. We expect that more experienced participants need less time, rotations, distance, direction changes or impact to reach the goal of a successful intubation compared to more inexperienced participants or novices.
We also want to evaluate if there is a positive effect of deliberate practice with the ORSIM on anaesthesiologists fiberoptic intubation skills. We expect that with deliberate practice on the ORSIM, anaesthesiologists improve their skills compared to the group who isn't allowed to practice.

Who can participate?
Healthy volunteers who work within the AMC department of anaesthesia as anaesthesia residents, consultants or anaesthetic nurses

What does the study involve?
For the control group it involves performing procedures on the ORSIM at the start, after 6 and 12 months only. The intervention group has to perform the same procedures on the ORSIM at the start, after 6 and 12 months but they also had to practice every 6 weeks in between.

What are the possible benefits and risks of participating?
The benefits are improving personal skills through practice and there are no risks.
The study is run from a single center, university hospital and starts in May 2018 and is expected to run until July 2019. There is no funding needed for this study and the main contact is M. van Haperen, consultant anesthesist

Where is the study run from?
Academic Medical Centre Amsterdam (The Netherlands)

When is the study starting and how long is it expected to run for?
March 2018 to July 2019

Who is funding the study?
Academic Medical Centre Amsterdam (The Netherlands)

Who is the main contact?
Maartje van Haperen, m.vanhaperen@amsterdamumc.nl

# Contact information

### Type(s)
Public

### Contact name
Miss Maartje van Haperen

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
W18_068

# Study information

### Scientific Title
Validation of the ORSIM simulator by randomizing healthy volunteers, consisting of anesthetic nurses, anesthetic residents and consultant anesthesiologists, between control or intervention group (participants practice on the ORSIM for 10 minutes every six weeks) as an assessment

method of anesthetists intubation skills by flexible bronchoscopy, through comparing results generated by the ORSIM simulator based on participants' level of experience and effect of training through comparing results of the participants in the intervention and control group

## Acronym
ORSIM study

## Study objectives
Gaining experience in awake fiberoptic intubation is difficult due to a lack of adequate training opportunities on difficult airways. Recently the ORSIM is a bronchoscopy simulator which contains multiple difficult airways is being developed. Within this study we want to evaluate if the ORSIM is a valid method to test anaesthesiologists fiberoptic intubatie skills. We expect that more experienced participants need less time, rotations, distance, direction changes or impact to reach the goal of a successful intubation compared to more inexperienced participants or novices.
We also want to evaluate if there is a positive effect of deliberate practice with the ORSIM on anaesthesiologists fiberoptic intubatie skills. We expect that with deliberate practice on the ORSIM, anaesthesiologists improve their skills compared to the group who isn't allowed to practice.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 6/3/2018 METC (Medical Ethics Review Committee) of the Academical Medical Center (Meibergdreef 9, 1100DD, Amsterdam, The Netherlands; +31 20-5667389; mecamc@amc.uva.nl), ref: W18_068

## Study design
Single center interventional randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Awake fiberoptic intubation

## Interventions

Participants consisting of three different levels of experience (expert, intermediate and novice) were all asked to perform the same procedures on the ORSIM after which they were randomised through lottery in either the control or intervention group. The intervention group was asked to practice every 6 weeks on the ORSIM during the whole study period of a year. Both groups were asked to perform the same procedures, partly different procedures compared to the first measurement to avoid learning by heart of the procedures, on the ORSIM at 6 months and 12 months time.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
1. Goals reached, duration, rotation, distance, direction changes and impact including an assessment of own skills as measured by the ORSIM simulator at baseline, 6 months and 12 months
2. Amount of flexible bronchoscopic intubations, using a visual analogue score (VAS) at baseline, 6 months and 12 months

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
01/03/2018

### Completion date
31/07/2019

## Eligibility

### Key inclusion criteria
Anaesthesiology residents, consultant anaesthetist and anaesthetic nurses

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Both

### Target number of participants
72 in total divided in 3 groups of 24 participants per group

### Total final enrolment
76

### Key exclusion criteria
Does not meet inclusion criteria

**Date of first enrolment**
01/05/2018

**Date of final enrolment**
01/07/2019

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Academical Medical Centre (AMC)**
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

# Sponsor information

**Organisation**
Academic Medical Center

**Sponsor details**
Department of Anesthesia
Meibergdreef 9
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1105 AZ
+31 (0)20-5669111
b.preckel@amsterdamumc.nl

**Sponsor type**
Hospital/treatment centre

**Website**
https://www.amc.nl/web/Zorg.htm

**ROR**
https://ror.org/03t4gr691

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Academisch Medisch Centrum

**Alternative Name(s)**
Academic Medical Center, AMC

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Netherlands

# Results and Publications

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

**Intention to publish date**
01/12/2023

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version 1 | 14/02/2018 | 13/09/2022 | No | No |
| Results article | | 09/08/2023 | 06/08/2024 | Yes | No |