

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

Submission date 01/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2024	Condition category Respiratory	<input type="checkbox"/> 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 anesthesiologist

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

ORCID ID

<http://orcid.org/0000-0002-0724-330X>

Contact details

Academic Medical Centre
Department of Anaesthesia
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 626724900
m.vanhaperen@amsterdamumc.nl

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 anesthesiologists 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 anesthesiologists 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 anesthesiologists fiberoptic intubation skills. We expect that with deliberate practice on the ORSIM, anesthesiologists 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 Academic 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

Amsterdam

Netherlands

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