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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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single center interventional randomised controlled trial

Study type(s)
Other

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/07/2019

Eligibility

Key inclusion criteria
Anaesthesiology residents, consultant anaesthetist and anaesthetic nurses

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academisch Medisch Centrum

Alternative Name(s)
Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

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?
Results article		09/08/2023	06/08/2024	Yes	No
Protocol file	version 1	14/02/2018	13/09/2022	No	No