

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative study of complications during and after intubation in patients undergoing surgery by direct and video laryngoscopy in Fatemi hospital in 1397 and 1398

Protocol summary

Study aim

Determine the complications during and after intubation in patients undergoing surgery by direct and video laryngoscopy in Fatemi hospital in 1397 and 1398

Design

Two arm parallel group randomised trial with blinded intra operative and post operative complications of Classic intubation and Video Laryngoscope Intubation

Settings and conduct

In this study, patients were divided into two groups of Classic Intubation and Video Laryngoscopy Intubation. Before dividing, for the first year residents of the anesthesiology, theoretical and practical classes on the mannequin are formed by the laryngoscope in the skill lab. Then by the anesthesiologist done direct laryngoscopy by three patients(Classic) and done video laryngoscopy by three patients. After completing the training and obtaining the minimum necessary skills for laryngoscopy, the residents are under the supervision of a senior resident or anesthesiologist intubation by General anesthesia in the same induction. For residents of each group, the number of successful intubations and the time of each intubation was recorded. If the time lasts more than 25 seconds or with the approval of the senior resident or anesthesiologist the tube is not in the trachea failure is recorded.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years old with ASA 1 or 2 which conditions are General Anesthesia by Intubation ; Emergency patients with anatomical disorders of the face or cardio pulmonary disease

Intervention groups

In this study, patients were randomly selected according to the criteria for entering the study and randomly divided to two groups of Classic Intubation and Video Laryngoscope Intubation

Main outcome variables

Hemodynamic status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190614043888N1**

Registration date: **2019-11-08, 1398/08/17**

Registration timing: **prospective**

Last update: **2019-11-08, 1398/08/17**

Update count: **0**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Pedram Golestaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3662 8970

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of complications during and after intubation in patients undergoing surgery by direct and video laryngoscopy in Fatemi hospital in 1397 and 1398

Public title

Comparative study of complications during and after intubation in patients undergoing surgery by direct and video laryngoscopy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient with condition of General Anesthesia by Intubation Patient satisfaction for participate in the study
The patient ASA is 1 and 2 Candidate for Elective Surgery
Age of patients between 18 till 70 years old

Exclusion criteria:

Change in Intubation for example Rapid Sequence Intubation Emergent patient Anatomical disorders of mouth or tongue or face The patient has a Cardio pulmonary disease The patient has a Cold

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people will be divided into two groups by random number table. According to this table, people in the couple's home will fall into the videolaryngoscope group and those in the individual home will be in the laryngoscopic group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients entered the study after obtaining satisfaction without the methodological knowledge of Intubation, divided into two groups of Classic Intubation and Video Laryngoscope Intubation

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Ardabil University of Medical Sciences

Street address

Daneshghah Ave, Ardabil University of Medical Sciences

City

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Province

Ardabil

Postal code

5618985991

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.ARUMS.REC.1398.041

Health conditions studied**1****Description of health condition studied**

In the study of Lyon et al., A randomized study between two groups of Direct laryngoscope and Video laryngoscope in emergent patients was done. Two groups of trained students, one group of Video laryngoscope and the others of Direct laryngoscope used. 85 patients who needed emergency intubation were included in the study. Finally, in terms of the duration of intubation, the mean intake in Direct laryngoscopy who had the mean time 25.9 second and the other group was 30.4 second. Regarding the shorter time in Direct laryngoscopy, but no statistically significant difference. (P value > 0.05)
Regarding the success rate of intubation in the above two methods, the success rate of intubation was in the Video laryngoscope 94.7% and in the Direct laryngoscope 86.1% but that was not statistically significant.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Duration of Intubation and its success rate

Timepoint

Intra intubation

Method of measurement

Stopwatch, Seeing

Secondary outcomes

1

Description

Hemodynamic status

Timepoint

Intra Intubation and 4 and 12 hours after operation

Method of measurement

Barometer, Questionnaire

Intervention groups

1

Description

Intervention group: Patients who need surgery under video Laryngoscopy are intubated. Laryngoscope for first year anesthesia assistants Theoretical and practical classes in the classroom and training on mannequins in skill lab. After the training is over, Students are divided into two groups randomly assigned to Video laryngoscope intubation by general anesthesia under the supervision of their assistant.

Category

Prevention

2

Description

Control group: Patients who need surgery under Direct Laryngoscopy are intubated. After the training is over, Students are divided into two groups randomly assigned to Direct laryngoscope intubation by general anesthesia under the supervision of their assistant.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital

Full name of responsible person

Pedram Golestaneh

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No. 20, Omid Alley (17th Alley), Valli St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mohsen Sagha

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Student Research Committee, Ardabil University of Medical Sciences, University St., Ardabil

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Pedram Golestaneh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on how the study is performed and the results of the study are shared

When the data will become available and for how long

Start of access period 12 months after the results are published

To whom data/document is available

All students and researchers working in academic institutes and universities

Under which criteria data/document could be used

Using of the method and results of the study

From where data/document is obtainable

Student Research Committee of Ardabil University of Medical Sciences

What processes are involved for a request to access data/document

With a visit of Ardabil University of Medical Science, Refer to the Student Research Committee, then the student research projects registration system is accessible

Comments