

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the intubation success rate in video laryngoscopy versus direct laryngoscopy in patients with philadelphia collar

Protocol summary

Summary

Objective: Comparing intubation success rate in video laryngoscopy versus direct laryngoscopy in patients with Philadelphia collar. Design: Single-center prospective randomized controlled trial. Setting and Conduct: Dr.Shariati Hospital Operating Room. Participants: 172 patients with cervical collar undergoing surgery under general anesthesia will be enrolled. Inclusion criteria: patients with Philadelphia collar aged 18 to 60 years; American Society of Anesthesiologists physical status 1, 2. Exclusion criteria: musculoskeletal disorders; emergency surgery; impaired ventilation. Intervention: After entering the operating room, patients will be divided into two different groups named A and B based on the table of random numbers. Standard monitoring will be established for all the patients entering the operating room, induction of anesthesia will be given with 4 µg/kg fentanyl and 2.5 mg/kg and 1 mg stat propofol by an anesthesiologist, and 0.5 mg/kg atracurium will be used to facilitate the intubation. After induction of anesthesia for all patients, oral airway will be used to facilitate ventilation and the patient will be ventilated by bag and mask. After recording the Train of Four, video laryngoscope in Group A and Macintosh laryngoscope in Group B will be used for intubation. Variables: 1- Intubation time: time required for intubation; 2- Number of intubation attempts; 3- CORMACK of the patients; 4- Oral and dental injuries; 5- Coughing during extubation; 6- Complications during extubation including: soft tissue injuries; dental injuries; airway spasm; 7- Heart Rate, Blood Pressure (Baseline, 30 seconds and 1 and then 3 minutes after intubation); 8- Sore throat in patients in the ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062728668N1**

Registration date: **2016-08-23, 1395/06/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-23, 1395/06/02

Registrant information

Name

Amin Karami

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

–

Email address

a-karami@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research-Tehran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the intubation success rate in video laryngoscopy versus direct laryngoscopy in patients with philadelphia collar

Public title

The success rate of intubation in patients with neck injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with Philadelphia collar aged 18 to 60 years; American Society of Anesthesiologists physical status 1,2; surgery under general anesthesia
Exclusion criteria: diabetes mellitus; rheumatoid arthritis; obstructive sleep apnea; surgery on the head and neck; musculoskeletal disorders; poor oral health; emergency surgery; cardiovascular disease; having a beard; impaired ventilation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **172**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Research deputy, Ethics Committee of Tehran University of Medical Sciences, 6th floor, Tehran University of Medical Sciences building, Ghods St, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2016-05-03, 1395/02/14

Ethics committee reference number

IR.TUMS.REC.1395.2540

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

intubation

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes**1****Description**

intubation success rate

Timepoint

after intubation

Method of measurement

capnograph and anesthesiologist's comment

Secondary outcomes**1****Description**

Neck circumference

Timepoint

Before intubation

Method of measurement

Measuring with a meter tape

2**Description**

heart rate

Timepoint

baseline; 30 seconds; 1 minute; 3 minutes after intubation

Method of measurement

device

3**Description**

mean arterial pressure

Timepoint

baseline; 30 seconds; 1 minute; 3 minutes after intubation

Method of measurement

device

4**Description**

CORMACK

Timepoint

During intubation

Method of measurement

through observation

5

Description

Duration of intubation

Timepoint

Method of measurement

chronometer

6

Description

number of intubation attempts

Timepoint

Method of measurement

anesthesiologist's comment

7

Description

oral and dental injury

Timepoint

After extubation

Method of measurement

Through observation

8

Description

cough during extubation

Timepoint

In the interval of 3 minutes after extubation

Method of measurement

Observation of coughing

9

Description

temporomandibular distance

Timepoint

Before intubation

Method of measurement

Measuring with a ruler

Intervention groups

1

Description

In control group intubations are done using direct laryngoscopy in which rigid laryngoscope is used to expose the laryngeal inlet under direct vision to facilitate intubation.

Category

Prevention

2

Description

in intervention group intubations are done using video laryngoscope. Video laryngoscope utilizes video camera technology to visualize airway structures and facilitate endotracheal intubation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research-Tehran University of Medical Sciences

Full name of responsible person

Dr. Masud Yunesian

Street address

Vice Chancellor for research , Tehran University of Medical Sciences Tehran Tehran, Islamic Republic of Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research-Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Dr Shariati Hospital

Full name of responsible person

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Assistant Professor of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty