

# 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**

Tehran university of medical science

#### **Full name of responsible person**

Dr. Amin Karami

#### **Position**

intern

#### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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Assistant Professor of Anesthesiology

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## Person responsible for updating data

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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*