

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the hemodynamic changes of urotracheal intubation in patients with a history of hypertension by direct laryngoscopy with the Macintosh blade of the video laryngoscope

#### Protocol summary

##### Study aim

Comparison of the hemodynamic changes of urotracheal intubation in patients with a history of hypertension by direct laryngoscopy with the Macintosh blade of the video laryngoscope

##### Design

This study will be conducted as a randomized clinical trial (blocks of four), double-blind, with parallel groups, without a control group, and phase 2-3, with the participation of 80 patients.

##### Settings and conduct

This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without a control group and phase 2-3 and with the participation of 80 ERCP candidates referred to Imam Reza Hospital (Tabriz) will be done.

##### Participants/Inclusion and exclusion criteria

The criteria for entering the study include: patients with high blood pressure, drug control of blood pressure and candidates for elective surgery, and the criteria for exiting the study include: patients with underlying diseases other than high blood pressure and lack of consent to participate in the present study.

##### Intervention groups

Patients will be randomly assigned to the group of video laryngoscope (i.e. glidescope) and normal laryngoscopy with Macintosh. After patients enter the operating room, an intravenous (IV) cannula is placed and blood pressure and heart rate are non-invasively monitored continuously with a multipurpose monitor. Baseline values of blood pressure and heart rate will be recorded after a 5-minute stabilization period. Blood pressure and heart rate will be recorded immediately after induction (post-induction values), at intubation and every minute for the first 5 minutes after intubation and will be compared between the two groups.

##### Main outcome variables

Hemodynamic status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N34**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

##### Registration date

2023-08-28, 1402/06/06

##### Registrant information

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-20, 1402/06/29

##### Expected recruitment end date

2023-11-20, 1402/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the hemodynamic changes of urotracheal intubation in patients with a history of hypertension by direct laryngoscopy with the Macintosh blade of the video laryngoscope

**Public title**

Hemodynamic changes of urotracheal intubation in patients with a history of hypertension by direct laryngoscopy with the Macintosh blade of the video laryngoscope

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with high blood pressure Pharmacological control of blood pressure Candidate for elective surgery

**Exclusion criteria:**

Patients with underlying diseases other than high blood pressure Lack of consent to participate in the present study

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The thesis results analyst who analyzed the expected outcome and also the participants remained unaware of the type of procedure performed and were blind during the study; Therefore, this study was conducted in a double-blind manner.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Imam Reza Hospital, Azadi Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665631

**Approval date**

2023-08-02, 1402/05/11

**Ethics committee reference number**

129

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

Hemodynamic status

**ICD-10 code**

R03

**ICD-10 code description**

Abnormal blood-pressure reading, without diagnosis

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

Hemodynamic status

**Timepoint**

Once every minute. 2 minutes before the start of anesthesia and up to 5 minutes after the end of anesthesia

**Method of measurement**

Hemodynamic status monitoring device

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Patients of this group will be intubated with the help of a video laryngoscope (i.e., a glidescope). After patients enter the operating room, an intravenous (IV) cannula is placed and blood pressure and heart rate are non-invasively monitored continuously with a multipurpose monitor. Baseline values of blood pressure and heart rate will be recorded after a 5-minute stabilization period. Blood pressure and heart rate will be recorded immediately after induction (post-induction values), at intubation and every minute for the first 5 minutes after intubation and will be compared between the two groups.

### Category

Prevention

## 2

### Description

Control group: Patients of this group will be intubated using a common laryngoscope (Macintosh). After patients enter the operating room, an intravenous (IV) cannula is placed and blood pressure and heart rate are non-invasively monitored continuously with a multipurpose monitor. Baseline values of blood pressure and heart rate will be recorded after a 5-minute stabilization period. Blood pressure and heart rate will be recorded immediately after induction (post-induction values), at intubation and every minute for the first 5 minutes after intubation and will be compared between the two groups.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital

#### Full name of responsible person

Mehdi Nazari

#### Street address

Imam Reza Hospital, Azadi Ave

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

6165665631

#### Phone

+98 21 3335 5921

#### Email

mghanbabayi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Abolghasem Jouyban

#### Street address

Shahid Madani Hospital, Azadi Ave

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5165665631

#### Phone

+98 41 3335 7310

#### Email

Ajouyban@hotmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Mehdi Khanbabayi Gol

#### Position

MSc in Nursing Education

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

Imam Reza Hospital, Azadi Ave

#### City

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#### Province

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#### Postal code

5981764863

#### Phone

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#### Fax

#### Email

Khanbabayimehdi69@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Khanbabayi Gol

**Position**

MSc in Nursing Education

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

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**Position**

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**Email**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available