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)

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+98 41 3334 7054

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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

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Imam Reza Hospital, Azadi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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