Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the hemodynamic responses to laryngoscopy and tracheal intubation with glidescope or Macintosh laryngoscope in severe preeclamptic patients undergoing cesarean delivery

Protocol summary

Study aim

Comparison of the hemodynamic responses including blood pressure changes, heart rate, and heart rhythm in the two laryngoscopy techniques of glideoscope and Macintosh

Design

A clinical trial in two groups of study and control group, with parallel groups, single blind, randomized

Settings and conduct

In Tabriz Alzahra Hospital , 70 pregnant women were randomly assigned to two groups of 35 subjects, using Randlist online software. In the study group, the intubation was performed with a glidescope and in the control group with a Macintosh laryngoscope. In this study, patients were blinded to intubation method.

Participants/Inclusion and exclusion criteria

Include criteria: Women aged 18 to 40 years old with a term (more than 37-weeks) pregnancy with severe pre-eclampsia with Mallampati degree1 and 2 who are candidates for cesarean section and have Informed consent to enter the study. Exclude criteria: Twins pregnancy, Body mass index (BMI) greater than 30, Higher Mallampathi grade, Maternal diseases, The recent use of vasoactive, Cervical movement limitation, Coagulation disorder, Eclampsy.

Intervention groups

Patients were randomly divided into two groups of 35 subjects. After general anesthesia, in the study group, intubation is performed with a glidescope and in the control group with a Macintosh laryngoscope.

Main outcome variables

Blood pressure changes; Heart rate changes; Cardiac rhythm changes; Number of attempts to intubate; The time of intubation; Postoperative side effects of tracheal intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110712007013N20**
Registration date: **2018-10-16, 1397/07/24**
Registration timing: **retrospective**

Last update: **2018-10-16, 1397/07/24**
Update count: **0**

Registration date

2018-10-16, 1397/07/24

Registrant information

Name
Simin Atashkhoei

Name of organization / entity
Tabriz University of Medical Siences

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Iran (Islamic Republic of)

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atashkhoii@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the hemodynamic responses to laryngoscopy and tracheal intubation with glidescope or Macintosh laryngoscope in severe preeclamptic patients undergoing cesarean delivery

Public title
Comparison of the hemodynamic responses in tracheal intubation with glidescope or Macintosh in severe preeclampsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Term pregnant women Age range 18-40 years old Candidates for elective or urgent cesarean section Severe preeclampsia Mallampati score I or II in preoperative visit informed consent

Exclusion criteria:
Mallampati score III or IV in preoperative visit Maternal co-existing disease History of cervical spine deformity or cervical motion limitation Eclampsia Coagulation disorder Body mass index (BMI) >30kg/m2 Recent use of vasoactive drugs

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control groups by Randlist online software

Blinding (investigator's opinion)
Single blinded

Blinding description
Single Blinded All patients participating in this study are blind to the type of laryngoscopy with a glidescope or Macintosh.

Placebo
Not 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
Department of Anesthesiology, Alzahra hospital, South artesh street

City
Tabriz

Province
East Azarbaijan

Postal code
5174815811

Approval date
2018-04-16, 1397/01/27

Ethics committee reference number
IR.TBZMED.REC.1397.048

Health conditions studied

1

Description of health condition studied
Severe preeclampsia

ICD-10 code
O14.1

ICD-10 code description
Severe pre-eclampsia

Primary outcomes

1

Description
Hemodynamic responses to laryngoscopy with Glidescope(Non-invasive blood pressure (systolic, diastolic and mean arterial), heart rate and heart rhythm of the mother)

Timepoint
Before induction of anesthesia (basic values), 30 seconds after administration of induction drugs, 15 seconds after the start of laryngoscopy, and then every 1 minute to 5 minutes after the tracheal intubation

Method of measurement
Non-invasive blood pressure (systolic, diastolic and mean arterial), heart rate, and heart rhythm are measured using the Datex Ohmeda S / 5 Anesthesia Machine and will be recorded in the checklist for this purpose.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After 3 minutes preoxygenation with 100% O2 , general anesthesia is induced by Rapid

sequence induction. After 60 seconds, the intubation is done by the Glidescope® videolaryngoscope [GVL, (Glidescope®, Saturn Biomedical Systems Inc., Canada)]and the tracheal tube inserted.

Category

Treatment - Devices

2

Description

Control group:After 3 minutes preoxygenation with 100% O2 , general anesthesia is induced by Rapid sequence induction. After 60 seconds, the intubation is done by the laryngoscope of the Macintosh blade 3 and the tracheal tube inserted. Intubation is performed by a fix anesthetist with more than 50 intubations history.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Simin Atashkhoyi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

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No 2 Central Building, International Relations Office, Tabriz University of Medical Sciences, University Street, Tabriz

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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

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

Simin Atashkhoyi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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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