

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparative evaluation direct laryngoscopy versus Glidescope for the purpose of laryngoscopy management and intubation in candidates of caesarean delivery with general anesthesia

Protocol summary

Study aim

Determining and comparing the direct laryngoscopy versus Glidescope for the purpose of laryngoscopy management and intubation in candidates of caesarean delivery with general anesthesia

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 90 patients

Settings and conduct

In this randomized double-blind clinical trial, 90 eligible patients referred to Beheshti Hospital in Isfahan will be included in the study and randomly divided into two groups. The first group will undergo direct intubation and the second group will be intubated by GlideScope video. Then, hemodynamic parameters of patients, laryngoscopy time, and the number of attempts for intubation between the two groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria consisted of pregnant women that were candidates for cesarean section under general anesthesia, with the American Society of Anesthesiologists (ASA) score of one or two, the gravidity of one or two, and Intubation Difficulty Scale (IDS) score of equal or less than 5. exclusion criteria consisted of the thyromental distance (TMD) was less than 6 cm, the neck circumference (NC) was equal or more than 43 cm, patients with increased intracranial pressure, any airway pathology, cervical spinal cord injury, and requirement for rapid induction.

Intervention groups

The first intervention group: Patients in the first group underwent intubation using the direct Macintosh laryngoscope with Macintosh blade No. 3. The second intervention group: Patients in the second group underwent intubation using GlideScope video laryngoscope.

Main outcome variables

Hemodynamic parameters; Laryngoscopy time; Number of attempts for intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N44**

Registration date: **2021-10-06, 1400/07/14**

Registration timing: **retrospective**

Last update: **2021-10-06, 1400/07/14**

Update count: **0**

Registration date

2021-10-06, 1400/07/14

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

2021-04-21, 1400/02/01

Actual recruitment end date

2021-08-22, 1400/05/31
Trial completion date
2021-08-22, 1400/05/31

Scientific title
Comparative evaluation direct laryngoscopy versus Glidescope for the purpose of laryngoscopy management and intubation in candidates of caesarean delivery with general anesthesia

Public title
Comparison of direct laryngoscopy versus Glidescope for the purpose of laryngoscopy management and intubation in candidates of caesarean delivery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women that were candidates for cesarean section under general anesthesia Class I and II classification of the American Society of Anesthesiologists The gravidity of one or two Intubation Difficulty Scale (IDS) score of equal or less than 5
Exclusion criteria:
The thyromental distance (TMD) was less than 6 cm The neck circumference (NC) was equal or more than 43 cm Patients with an increased intracranial pressure Any airway pathology Any cervical spinal cord injury requirement for rapid induction

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 90 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". These numbers are randomly divided into two groups A (first intervention) and B (second intervention). Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
To meet the blinding condition in the study, the anesthesiologist that was responsible for performing intubation did not take part in the collection of patients' information due to knowledge of the type of intervention

in each of the two groups; however, the patient, the patient data collector, and the statistician were not aware of the type of intervention in two groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfahan
Postal code
8179964167

Approval date
2019-03-02, 1397/12/11

Ethics committee reference number
IR.MUI.MED.REC.1397.282

Health conditions studied

1

Description of health condition studied
Elective cesarean section

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Number of attempts for intubatio

Timepoint
At the time of intubation

Method of measurement
Number of attempts

2

Description
Time-to-intubation

Timepoint

At the time of intubation

Method of measurement

from the time the laryngoscope was inserted into the mouth to the filling of the endotracheal tube cuff and the confirmation of the insertion of the intubation with capnography

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

At the beginning of the study (baseline) and before laryngoscopy and in the first, third, fifth, and tenth minutes after laryngoscopy

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

At the beginning of the study (baseline) and before laryngoscopy and in the first, third, fifth, and tenth minutes after laryngoscopy

Method of measurement

Monitoring device

3

Description

Mean Arterial Pressure

Timepoint

At the beginning of the study (baseline) and before laryngoscopy and in the first, third, fifth, and tenth minutes after laryngoscopy

Method of measurement

Monitoring device

4

Description

Heart rate

Timepoint

At the beginning of the study (baseline) and before laryngoscopy and in the first, third, fifth, and tenth minutes after laryngoscopy

Method of measurement

Monitoring device

Intervention groups

1

Description

The first intervention group: Patients in the first group underwent intubation using the direct Macintosh laryngoscope with Macintosh blade No. 3.

Category

Treatment - Devices

2

Description

The second intervention group: Patients in the second group underwent intubation using GlideScope video laryngoscope.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Azim Honarmand

Street address

Motahari Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

honarmand@med.mui.a.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

honarmand@med.mui.a.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

honarmand@med.mui.a.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Jafari

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Ailin.babaei@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

y. If you do not want to provide more explanation please enter "There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available