Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparative study of the effects of rapid sequence induction(RSI) intubation and localized laryngeal recurrent nerve block with fentanyl on hemodynamic changes in patients with hemodynamic disorders

Protocol summary

Study aim

Determination and comparison of stability assessment of hemodynamic parameters between rapid sequence induction (RSI) and localized laryngeal recurrent nerve block with fentanyl

Design

A randomized single-blinding clinical trial, with the parallel groups

Settings and conduct

A single-blind clinical trial study will be performed on 70 patients with hemodynamic disorders. TThese patients will be anesthetized in two different ways. Then the stability of hemodynamic parameters is evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria included hemodynamic disorders in the form of arterial systolic pressure drop to less than 90 mm Hg, the age of over 18 yrs. and under 65 yrs., no contraindications to succinylcholine, ASA I and II, the degree of Mallampati between 1-4, the attendant consent to participate the patient in the study. Exclusion criteria also include the chance of difficult intubation (small chin, large tongue, and short neck), history of pharyngeal or tracheal surgery, history of asthma or allergies and infection at the site of local blockade. Also, patients with cardiac respiratory arrest who require intubation and patients with hemodynamic disorders who have a history of taking antihypertensive drugs were excluded.

Intervention groups

In this study, in the first intervention group, fentanyl 3 mcg/kg, etomidate 0.3 mg/kg and succinylcholine 1.5 mg/kg will be administered. One minute afterward, intubation will be performed. In the second intervention group, after local anesthesia with Xyla-p cream, fentanyl is slowly injected before the onset of local block. Then localized blockage of laryngeal recurrent nerve and superior laryngeal nerve will be used. Intubation will then be performed.

Main outcome variables

Blood pressure; Heart rate; Respiration rate; Oxygen saturation percentage; Success in endotracheal intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N2**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **prospective**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date

2020-09-16, 1399/06/26

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effects of rapid sequence induction(RSI) intubation and localized laryngeal recurrent nerve block with fentanyl on hemodynamic changes in patients with hemodynamic disorders

Public title
The effects of rapid sequence induction and localized laryngeal recurrent nerve block with fentanyl on hemodynamic changes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hemodynamic disorder in the form of arterial systolic pressure drop to less than 90 mm Hg The age of over 18 years old and under 65 years old No contraindications to taking succinylcholine ASA I or II A degree of Malampati between I-IV The Consent of the attendant to participate the patient in the study
Exclusion criteria:
Chance of difficult intubation (small chin, large tongue, short neck, etc.) A history of throat or tracheal surgery A history of asthma or allergies The presence of infection at the site of the local block Patients with cardiac respiratory arrest who require intubation by Crush method. Patients with hemodynamic disorders who have a history of taking antihypertensive drugs.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
We randomly select 70 eligible patients. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, due to the different use of two methods of rapid sequence induction (RSI) and localized laryngeal recurrent nerve block with fentanyl, the emergency medical assistant and the patient are aware of the type of intervention. However, the data collector and data analyst did not know the type of patient grouping.
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
Isfehan
Postal code
8179964167
Approval date
2020-05-13, 1399/02/24
Ethics committee reference number
IR.MUI.MED.REC.1399.147

Health conditions studied

1

Description of health condition studied
Hemodynamic Disorders
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood Pressure
Timepoint
Before, 5, 10, 20 and 30 minutes after intubation
Method of measurement
Monitoring device

2

Description
Respiratory rate
Timepoint

Before, 5, 10, 20 and 30 minutes after intubation

Method of measurement

Monitoring device

3

Description

Pulse rate

Timepoint

Before, 5, 10, 20 and 30 minutes after intubation

Method of measurement

Monitoring device

4

Description

Oxygen saturation percentage

Timepoint

Before, 5, 10, 20 and 30 minutes after intubation

Method of measurement

Monitoring device

Secondary outcomes

1

Description

Success in endotracheal intubation

Timepoint

After intubation

Method of measurement

Observation

2

Description

Incidence of complications

Timepoint

After intubation

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: In first group, fentanyl 3 mcg/kg, etomidate 0.3 mg/kg and succinylcholine 1.5 mg/kg will be administered to prevent fasciculation. One minute afterwards, intubation will be performed.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, localized blockage of laryngeal recurrent nerve and superior laryngeal nerve with fentanyl will be used. For this purpose, first apply topical Xyla-p cream to the skin of the injection sites, and by placing a plastic cover on it, the onset of its effect is shortened and the strength of its effect is increased. Then fentanyl at a dose of 1 µg/kg is slowly injected intravenously 1 to 2 minutes before the onset of topical block. Immediately after that, 2 puffs of 10% lidocaine spray will be administered in the oropharynx. Then blockade of the cricoid region and bilateral laryngeal recurrent nerve will be performed by injection of 2% lidocaine. This causes a cough that distributes and directs the local block. Finally, 2 minutes after the completion of local injection block (5 minutes after local block with oral spray), endotracheal intubation will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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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
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