Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of intra nasal remifentanil and lidocaine on heart rate and blood pressure during using laryngeal mask airway in induction of anesthesia with thiopental sodium

Protocol summary

Study aim
Comparison of the effect of intra nasal remifentanil and lidocaine on heart rate and blood pressure during using laryngeal mask airway in induction of anesthesia with thiopental sodium

Design
A double-blind randomized clinical trial with a total sample size of 60 patients

Settings and conduct
After approval of this study by the Ethics Committee of Isfahan University of Medical Sciences and informed consent of 60 eligible patients aged 18-80 years undergoing elective cataract surgery in Faiz Isfahan Medical Center in this prospective randomized double blind study. Patients were randomly divided into two groups of patients (lidocaine (1.5mg / kg) or fentanyl (1mg / kg) after induction of general anesthesia with 1.5mg / kg of fentanyl and 5mg / kg / IV of thiopental fentanyl intranasal). 1mcg / kg (Inf group) or intranasal lidocaine, 1.5mg / kg (Inl group) up to 2cc volume.For each heart rate group [HR], systolic blood pressure [SBP], diastolic blood pressure [DBP], mean arterial pressure [MAP], and blood oxygen saturation [SPO2] at three different intervals; before drug administration, during the intervention A blind observer was recorded every 5 minutes and every 10 minutes in the recovery room.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients Candidate for Laryngeal Mask (18 to 85 years) Exclusion criteria:Risk of aspiration (gastric ulcer, gastroesophageal reflux disease, pregnancy), weight less than 40kg, 110kg, presence of pharyngeal oropharyngeal, inadequate pulmonary compliance, high airway resistance, cervical vertebrae, Sensitivity to any of the anesthetic drugs, and a history of musculoskeletal disease

Intervention groups
Group 1: Intranasal Remifentanil intake. Group 2: Intranasal Lidocaine intake

Main outcome variables
Heart rate Systolic blood pressure Diastolic blood pressure Median arterial blood pressure O2 saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N10**
Registration date: **2020-02-19, 1398/11/30**
Registration timing: **retrospective**

Last update: **2020-02-19, 1398/11/30**
Update count: **0**

Registration date
2020-02-19, 1398/11/30

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
hamidshetabi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-09, 1397/10/19

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
2019-01-09, 1397/10/19
Actual recruitment end date
2019-02-20, 1397/12/01
Trial completion date
2019-02-20, 1397/12/01

Scientific title
Comparison of the effect of intra nasal remifentanil and lidocaine on heart rate and blood pressure during using laryngeal mask airway in induction of anesthesia with thiopental sodium

Public title
Comparison of the effect of intra nasal remifentanil and lidocaine on heart rate and blood pressure during using laryngeal mask airway in induction of anesthesia with thiopental sodium
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients Candidate for Laryngeal Mask (18 to 85 years)
Exclusion criteria:
Risk of aspiration (gastric ulcer, gastroesophageal reflux disease, pregnancy), weight less than 40kg, 110kg, presence of pharyngeal oropharyngeal, inadequate pulmonary compliance, high airway resistance, cervical vertebrae,, Sensitivity to any of the anesthetic drugs, and a history of musculoskeletal disease
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The drugs are prepared by an anesthesiologist who did not know the patient group. Each patient receives a code by random allocation software and the codes are opened after the plan is completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs are prepared by an anesthesiologist who did not know the patient group. Each patient receives a code by random allocation software and the codes are opened after the plan is completed.
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
Isfahan University of medical sciences, Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-01-06, 1398/10/16
Ethics committee reference number
IR.MUI.MED.REC.1398.509

Health conditions studied

1

Description of health condition studied
Heart rate and blood pressure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Heart rate
Timepoint
Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 after laryngeal mask airway
Method of measurement
Electrocardiogram (EKG)

2

Description
Blood pressure
Timepoint
Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 after laryngeal mask airway
Method of measurement
Pressure gauge

3

Description

Mean arterial pressure

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 after laryngeal mask airway

Method of measurement

Pressure gauge

4

Description

Oxygen saturation percentage

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 after laryngeal mask airway

Method of measurement

Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients receive 5 ml / kg of Ringer fluid before induction of anesthesia and oxygen. After induction of general anesthesia with 5ml / kg intravenous thiopental sodium,they received 1mcg / kg intranasal remifentanil.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients receive 5 ml / kg of Ringer fluid before induction of anesthesia and oxygen.After induction of general anesthesia with 5 ml / kg of intravenous thiopental sodium, they received 1.5ml / kg intranasal lidocaine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz hospital

Full name of responsible person

Hamidreza shetabi

Street address

Feyz Hospital , Modares St

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3445 2034

Email

Hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaqayeq Haghjoo javanmard

Street address

Hizar jarib BLVD, Isfahan University of Medical Sciences and Health Services , Deputy of Research and Technology of the University

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 5149

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Hamidreza shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Feiz Hospital, Modarres St

City
Isfahan
Province
Isfehan
Postal code
7346181764
Phone
+98 31 3668 8138
Email
Hamidshetabi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Shetsbi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Feiz Hospital, Modarres St
City
Isfahan
Province
Isfehan
Postal code
81764734610
Phone
+98 31 3620 2020
Email
hamidshetabi@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Shetabi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Feiz Hospital, Modarres St
City
Isfahan
Province
Isfehan
Postal code
81764734610
Phone
+98 31 3620 2020
Email
hamidshetabi@med.mui.ac.ir

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