

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of intra nasal remifentanyl 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 remifentanyl 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 (Inf 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 Remifentanyl 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 remifentanyl 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 remifentanyl 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

AgeFrom **18 years** old to **85 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget 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

Isfahan

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 remifentanyl.

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
Isfahan

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
Isfahan

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
Isfahan
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
Isfahan
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
Isfahan
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