Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of remifentanil and lidocaine on controlling the cardiovascular response to laryngeal mask airway insertion following general anesthesia

Protocol summary

Study aim

Determination and comparison the effect of remifentanil with intravenous lidocaine in controlling the cardiovascular response to laryngeal mask airway insertion in general anesthesia

Design

Clinical trial with control group, double-blind, randomized, phase 2 in 60 patients

Settings and conduct

This double blind randomized clinical trial performs in Shahroud's Imam Hossein hospital. Patients with inclusion criteria, after justification and informed concern according simple randomization assigns to control or intervention group. Anesthetist, records the group's type in participant's questionnaire that has two portion with identical cod and then separates data recording portion and gives it to person who is responsible of outcome recording and is unaware of patient grouping. syringes of remifentanil and lidocaine will be ready in identical shape and volume

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female 18 - 60 years old - Open limbs surgery under general anesthesia - Class 1 and 2 of anesthesia risk (According to American society of anesthesiologist's classification) Exclusion criteria: Difficult LMA placements - Repeated attempts at LMA insertion - Prolonged (more than 30 seconds) LMA insertion

Intervention groups

Intervention group: Management of anesthesia in both groups are identical. Participants in intervention group after induction of anesthesia receives intravenous Remifentanil with a dose of 1.5 microgram/kg, and after 2 minutes ventilation Laryngeal Mask Airway will be inserted. Control group: participants in control group after induction of anesthesia receives intravenous Lidocaine with a dose of 1.5 mg/kg, and after 2 minutes ventilation Laryngeal Mask Airway will be inserted.

Main outcome variables

Systolic blood pressure, Diastolic blood pressure and Pulse rate before and after induction of anesthesia and following LMA insertion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181229042169N1**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Batool Chopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3234 2000

Email address

batool_chopani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-04-18, 1400/01/29

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

Scientific title
Comparison of remifentanil and lidocaine on controlling the cardiovascular response to laryngeal mask airway insertion following general anesthesia

Public title
Comparison of intravenous remifentanil and intravenous lidocaine in prevention of cardiovascular response to laryngeal mask airway insertionl following anesthesia in limbs surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female 18 - 60 years old Open limbs surgery under general anesthesia Class 1 and 2 of anesthesia risk (According to American society of anesthesiologist's classification)
Exclusion criteria:
Difficult LMA placements Repeated attempts at LMA insertion Prolonged (more than 30 seconds) LMA insertion
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple blind randomization Sixty identical sheets(30 control and 30 intervention) were mixed in a bag and randomly one sheet brings out and the patients assigns to one group according this sheet and then the sheet is left out.
Blinding (investigator's opinion)
Double blinded
Blinding description
Anesthesiologist and nurse anesthesia are aware of patient's group and this group is recorded in questionnaire by them. Questionnaire has two portion with identical cod. Nurse anesthesia separates data recording portion and gives it to person who is responsible of outcome recording and is unaware of patient grouping. syringes of remifentanil and lidocaine will be ready in identical shape and volume
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud university of medical sciences
Street address
Shahroud university of medical sciences , 7tir sq
City
shahroud
Province
Semnan
Postal code
36147-73947
Approval date
2017-03-06, 1395/12/16
Ethics committee reference number
IR.SHMU.REC.1395.184

Health conditions studied

1

Description of health condition studied
Open reduction and internal fixation of ulna and radiusfracture
ICD-10 code
S52.4
ICD-10 code description
Fracture of shaft of radius

Primary outcomes

1

Description
systolic Blood pressure
Timepoint
Before induction of anesthesia - after induction of anesthesia - and immediately after laryngeal mask airway insertion
Method of measurement
Non-invasive blood pressure measurement with Novin Saadat monitor.

2

Description
Diastolic blood pressure

Timepoint
Before induction of anesthesia - after induction of anesthesia - and immediately after laryngeal mask airway insertion
Method of measurement
Non-invasive blood pressure measurement with Novin Saadat monitor.

3

Description
Pulse rate
Timepoint
Before induction of anesthesia - after induction of anesthesia - and immediately after laryngeal mask airway insertion
Method of measurement
Non-invasive blood pressure measurement with Novin Saadat monitor.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: participants in intervention group after induction of anesthesia receives intravenous Remifentanil with a dose of 1.5 microgram/kg, and after 2 minutes ventilation Laryngeal Mask Airway will be inserted.
Category
Treatment - Drugs

2

Description
Control group: participants in control group after induction of anesthesia receives intravenous Lidocaine with a dose of 1.5 mg/kg, and after 2 minutes ventilation Laryngeal Mask Airway will be inserted.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Javad Nourian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Shahroud university of medical sience
Grant code / Reference number
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Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person

Dr Javad Nourian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

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

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