Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous remifentanil and lidocaine on the cardiovascular response to laryngoscopy and tracheal intubation under general anesthesia in open limbs surgery.

Protocol summary

Study aim
Determination and comparison of the effect of remifentanil with intravenous lidocaine in controlling the cardiovascular response to laryngoscopy and endotracheal intubation in general anesthesia
Design
Clinical trial with control group, double-blind, randomized, phase 2 in 60 patients
Settings and conduct
Sixty patients were divided into two intervention and control groups by double-blind method and this study was performed in the operating room
Participants/Inclusion and exclusion criteria
Open limb surgery under general anesthesia and the risk of one and two anesthesia Cases of difficult intubation and any problems with laryngoscopy and intubation
Intervention groups
A group of 30 people received Remy Fentanyl
Main outcome variables
Blood pressure Pulse rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200501047255N1**
Registration date: **2020-07-27, 1399/05/06**
Registration timing: **retrospective**

Last update: **2020-07-27, 1399/05/06**
Update count: **0**
Registration date
2020-07-27, 1399/05/06

Registrant information
Name
mohammadtaghi koochaki
Name of organization / entity
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Iran (Islamic Republic of)
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+98 26 3663 6813
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-11, 1399/02/22
Expected recruitment end date
2020-06-11, 1399/03/22
Actual recruitment start date
2020-05-14, 1399/02/25
Actual recruitment end date
2020-06-11, 1399/03/22
Trial completion date
2020-06-26, 1399/04/06

Scientific title
Comparison of intravenous remifentanil and lidocaine on the cardiovascular response to laryngoscopy and tracheal intubation under general anesthesia in open limbs surgery.

Public title
Comparison of intravenous remifentanil and intravenous lidocaine in prevention of cardiovascular response following laryngoscopy and tracheal intubation under genereal anesthesia in limbs surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Open limbs surgery under general anesthesia Class 1

and 2 of anesthesia risk (According to American society of anesthesiologist's classification),
Exclusion criteria:
Difficult intubation prolonged (more than 30 seconds) attempts at laryngoscopy Repeated attempts at laryngoscopy

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**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple blind randomization Which consists of 60 completely identical sheets and is written in 30 sheets of the control group and 30 sheets of intervention and each patient is divided by removing one sheet and the sheet is left out.

Blinding (investigator's opinion)
Double blinded

Blinding description
60 identical small ball(30 intervension and 30 control) in a bag used for randomization,for each patient one ball randomly took by anesthetist. patient, researcher and data collector were unaware of patient group.

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
2020-05-09, 1399/02/20

Ethics committee reference number
IR.SHMU.REC.1399.042

Health conditions studied

1

Description of health condition studied
Open reduction and internal fixation of ulna and radius fracture

ICD-10 code
S52.4

ICD-10 code description
Fracture of shaft of radius

2

Description of health condition studied
Open reduction of humerus fracture

ICD-10 code
S42.4

ICD-10 code description
Fracture of lower end of humerus

3

Description of health condition studied
Open reduction of tibia fractures

ICD-10 code
S82.3

ICD-10 code description
Fracture of lower end of tibia

Primary outcomes

1

Description
Blood pressure

Timepoint
Before induction of anesthesia and just following laryngoscopy and tracheal intubation

Method of measurement
Non-invasive blood pressure measurement with Novin Saadat monitor.

2

Description
Pulse rate

Timepoint
Before induction of anesthesia and just following laryngoscopy and tracheal intubation

Method of measurement
Non-invasive blood pressure measurement with Novin Saadat monitor.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30of parcipitants that received remifentanil with a dose of 2µg/kg
Category
Treatment - Drugs

2

Description
Control group: A group of 30 people who received 1.5 micrograms per kilogram of lidocaine weight.
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
Shahroud University of Medical Sciences
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Grant name
Grant code / Reference number
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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Specialist

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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