Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Specify the effect of intranasal and intravenous remifentanil on hemodynamic changes after induction and tracheal intubation and comparing with control group

Protocol summary

Study aim
Specify the effect of intranasal and intravenous remifentanyl on hemodynamic changes after induction and tracheal intubation and comparing with control group

Design
Clinical trial with control group with parallel and three-blind side randomized phases of Phase 2 on 180 patients. Random allocation method has been used for randomization.

Settings and conduct
Research on GA has been conducted using a 3-side blind method for participants who adjust the dose of the drug and injectors and people involved in collecting information and analyzers.

Participants/Inclusion and exclusion criteria
Criteria for entering the study patients with ASA1.2 with ages between 18 and 65 . Conditions for not entering the age of less than 18 or more than 65 ; drug addiction ; Allergy to the drug under study; ASA3,4 patients with severe heart and lung disorders; change anesthesia technique as needed; Severe bleeding and hemodynamic shock and the need to inject blood products and patients who are in the 3rd and 4th grade of kermek Liehan.

Intervention groups
1. Average systolic and diastolic arterial BP and HR at baseline times 1-3 minutes after anesthesia just before laryngoscopy at times 1-3-5-10 min after laryngoscopy 2. Complications of IV fentanyl and nasal on bradycardia (pulse less than 60) tachycardia (pulse greater than 100) hypotension (systolic pressure less than 90) Hypertension (systolic pressure greater than 140 and diastolic pressure greater than 90) 3. satisfaction score based on VAS criteria and its division into3 levels: low (0 to 3 points), medium (4 to 6) and high (7 to 10) after surgery. 4. O2 sat and capnography at baseline;1 to 3 min after anesthesia; just before laryngoscopy and at 1-3-5-10 min after laryngoscopy.

Main outcome variables
The effect of the drug on hemodynamic changes including blood pressure and heart rate;Laryngoscopic duration;Satisfaction ofsurgeon and patient;ABG ;VBG

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101211005362N24**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **retrospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date
2020-06-06, 1399/03/17

Registrant information

Name
Mohammadreza Safavi
Name of organization / entity
Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2020-03-18, 1398/12/28
Actual recruitment start date
2018-03-21, 1397/01/01
Actual recruitment end date
2020-03-10, 1398/12/20
Trial completion date
2020-03-10, 1398/12/20

Scientific title
Specify the effect of intranasal and intravenous remifentanil on hemodynamic changes after induction and tracheal intubation and comparing with control group

Public title
effect of remifentanil in general anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with ASA1.2 Patient between 18 to 65 years old Patients who need General anesthesia and larengoscopy and tracheal intubation
Exclusion criteria:
Patients under 18 or older than 65 years old Addicted patients Patients who have allergy to the drug noticed in this study Patient with ASA3.4
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **180**
Actual sample size reached: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
How to randomize in this study is done by simple randomization method using random allocation software which is an individual randomization unit and random sequencing using this software and based on the order provided to patients. For allocation concealment, the sequentially numbered ,sealed ,opaque envelopes or SNOSE method was used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The first person divides by simple non-random method / random allocation software into three groups with a total of 60 people.The second person in the treatment encodes 3 groups of intranasal and intravenous drugs and the same amount of normal saline volume. The other person also collects the information of each group without knowing the study group.Data analysis is also performed without the knowledge of the groups.
Placebo
Used
Assignment
Factorial
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
Hezar Jerib Ave.Isfahan University of Medical Sciences
City
isfahan
Province
Isfehan
Postal code
8614736441
Approval date
2020-05-17, 1399/02/28
Ethics committee reference number
IR.MUI.MED.REC.1399.154

Health conditions studied

1

Description of health condition studied
Hemodynamic changes after induction of anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean systolic and diastolic blood pressure and mean arterial blood pressure
Timepoint
Basic time (just before the intervention) 1-3 minutes after anesthesia just before laryngoscopy and 1-3-5-10 minutes after laryngoscopy
Method of measurement
Non-invasive manometer

2

Description
Heart rate
Timepoint
At baseline (before the intervention) 1 to 3 minutes after

anesthesia just before laryngoscopy and at 1-3-5-10 minutes after laryngoscopy.

Method of measurement

electro cardiogaraph

3

Description

Average of satisfaction score

Timepoint

after surgery

Method of measurement

Visual Analogue Scale

4

Description

Average of O2 saturation

Timepoint

Basic time (before the intervention) 1 to 3 minutes after anesthesia just before laryngoscopy and 1-3-5-10 minutes after laryngoscopy

Method of measurement

pulse oxymeter

5

Description

capnography

Timepoint

Basic time (before the intervention) 1 to 3 minutes after anesthesia just before laryngoscopy and 1-3-5-10 minutes after laryngoscopy

Method of measurement

capnograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group consisted of 60 recipients receiving 0.5 micrograms intravenous remifentanyl

Category

Treatment - Drugs

2

Description

Intervention group: The second group includes 60 recipients of nasal Remifentanyl in the amount of 4 micrograms per kilogram

Category

Treatment - Drugs

3

Description

Control group: Includes 60 people receiving the same amount of saline with intervention groups

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mohammadreza Safavi

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Sofe Ave, Isfahan

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8174675731

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Web page address

http://alzahra.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

SHagayegh Haghjoo Javanmar

Street address

Hezar Jerib Ave.

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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

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

Mohammadreza Safavi

Position

Professor of anesthesia

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study, all the documents can be shared after identifying the participants in the study.

When the data will become available and for how long

The time period for accessing the study data is December 30, 2020

To whom data/document is available

Data and other study documents will be available only to researchers working in academic and scientific

institutions

Under which criteria data/document could be used

Other researchers of research centers are provided with a letter of introduction from a reputable center and mention the goals ahead and the type of targeted analysis , if appropriate, information and study data can be reached.

From where data/document is obtainable

By presenting a valid letter of introduction based on the priority of scientific study organizations and referring to Dr. Mohammad Reza Safavi to the address of Isfahan Al-Zahra Hospital Boulevard and e-mail address: safavi@med.mui.ac.ir

What processes are involved for a request to access data/document

After submitting the request to the responsible person in charge of the study, if it is approved by the research deputy of Isfahan University of Medical Sciences and the approval of the anesthesia department, the research documents will be provided to the person.

Comments