Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the effect of infusion of two doses of remifentanil on bleeding rate, intraoperative hemodynamic changes, and complications after rhinoplasty after general anesthesia

Protocol summary

Study aim

Determining and comparing the effect of two doses of remifentanil infusion on bleeding volume, hemodynamic changes during surgery, and complications after rhinoplasty surgery.

Design

A randomized, triple-blinding clinical trial, with parallel groups, Phase 2-3 on 60 patients

Settings and conduct

In this three-blind randomized clinical trial study, 60 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into two groups. After general anesthesia, remifentanil infusion takes place at a rate of 50-100 mcg/kg and 100-150 mcg/kg will be prescribed in two groups, respectively. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention. Then the bleeding rate, hemodynamic parameters, and complications after surgery will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include the age group of 18 to 50 years, a candidate for rhinoplasty, with ASA class I or II (American Society of Anesthesiologists), and consent to participate in the study. Exclusion criteria include a history of a previous rhinoplasty, sensitivity to remifentanil, opioid abuse, bleeding disorder, and use of contraceptive methods.

Intervention groups

The first intervention group: In this group, after general anesthesia, remifentanil infusion is done at a rate of 50-100 mcg/kg. The second intervention group: in this group, after general anesthesia, remifentanil infusion takes place at a rate of 100-150 mcg/kg.

Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation(Spo2); Bleeding volume; Bradycardia; hypertension; nausea; Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N65**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of infusion of two doses of remifentanil on bleeding rate, intraoperative hemodynamic changes, and complications after rhinoplasty after general anesthesia

Public title

The effect of two doses of remifentanil on bleeding rate, intraoperative hemodynamic changes, and complications after rhinoplasty surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 18 to 50 years Candidate for rhinoplasty with class I and II ASA (American Society of Anesthesiologists) Consent to participate in the study

Exclusion criteria:

Having a history of previous rhinoplasty Having an allergy to remifentanil Opioid abuse Bleeding disorder Use of contraceptive methods

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, letter A is written on 30 sheets, letter B is written on 30 sheets, and each is placed in an envelope. Then, each eligible patient who consented to participate in the study is asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the two groups according to the envelope selected without the interference of the researcher.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to achieve the triple-blind study, different doses of remifentanil will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A and B. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

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

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-04-11, 1401/01/22

Ethics committee reference number

IR.MUI.MED.REC.1401.017

Health conditions studied

1

Description of health condition studied

Rhinoplasty surgery candidate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before induction of anesthesia, every ten minutes during operation and every ten minutes during recovery

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

Before induction of anesthesia, every ten minutes during operation and every ten minutes during recovery

Method of measurement
Monitoring device

3

Description
Heart beat
Timepoint
Before induction of anesthesia, every ten minutes during operation and every ten minutes during recovery
Method of measurement
Monitoring device

4

Description
Oxygen saturation (SPO2)
Timepoint
Before induction of anesthesia, every ten minutes during operation and every ten minutes during recovery
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Bleeding volume
Timepoint
During surgery
Method of measurement
Measurement of blood volume in suction

2

Description
Tachycardia
Timepoint
After surgery
Method of measurement
Heart rate more than 100 beats per minute

3

Description
Bradycardia
Timepoint
After surgery
Method of measurement
Heart rate less than 60 beats per minute

4

Description
Nausea and vomiting
Timepoint
After surgery
Method of measurement
Observational

Intervention groups

1

Description
First intervention group: In this group, after general anesthesia, remifentanil (Exir Pharmaceutical Company) infusion is done at a rate of 50-100 micrograms/kg.
Category
Treatment - Drugs

2

Description
Second intervention group: in this group, after general anesthesia, remifentanil(Exir Pharmaceutical Company) infusion takes place at a rate of 100-150 micrograms/kg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Hamidreza Shetabi
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
hamid.shetabi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

hamid.shetabi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

hamid.shetabi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa MohammadRezaei

Position

Non-faculty specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

mahsamohammadrezaei66@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available