

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of respiratory tidal volume on the required dose of remifentanyl to create controlled hypotension in rhinoplasty surgery

Protocol summary

Study aim

Determining the effect of respiratory tidal volume on the required dose of remifentanyl to create controlled hypotension in rhinoplasty surgery.

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2-3 on 40 patients

Settings and conduct

In this randomized double-blind clinical trial study, 40 eligible patients, referring to Al-Zahra and Kashani hospitals in Isfahan, will be included in the study and will be randomly divided into two groups. Then the patients will be divided according to the minimum and maximum respiratory tidal volume dose and will receive remifentanyl. Then the hemodynamic parameters and respiratory complications of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria include candidate patients for rhinoplasty, aged 18-65 years, weigh more than 50 kg, having an American Association of Anesthesiologists (ASA) class equal to I, and informed consent to participate in the study. Exclusion criteria include addiction to opioid products, comorbidity disease (such as respiratory and coagulation disease) and a history of allergy to the study drug.

Intervention groups

First intervention group: In this group, the minimum tidal volume is selected based on the ideal weight (6cc/kg). Then remifentanyl (according to routine) is given to cause hypotension and the appropriate dose is determined according to the patient's average blood pressure based on ideal body weight. The second intervention group: In this group, the maximum tidal volume is selected based on the ideal weight (10cc/kg). Then remifentanyl (according to routine) is given to cause hypotension and the appropriate dose is determined according to the patient's average blood pressure based on ideal body weight.

Main outcome variables

Blood pressure; Heart beat; Satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N71**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

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

2023-10-22, 1402/07/30

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of respiratory tidal volume on the required dose of remifentanyl to create controlled hypotension in rhinoplasty surgery

Public title

Effect of respiratory tidal volume on the required dose of remifentanyl to create controlled hypotension

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for rhinoplasty Age group 18-65 years Weight more than 50 kg American Society of Anesthesiologists (ASA) class is equal to I Informed consent to participate in the study

Exclusion criteria:

Being addicted to opioid products Having the comorbidity (such as respiratory and coagulation disease) History of allergy to the studied drug

Age

From **18 years** old to **65 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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 40 eligible rhinoplasty candidate patients are randomly selected. For this, the letter A is written on 20 sheets and the letter B is written on 20 sheets, and each of them is placed in an envelope. Each patients is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to achieve the double-blind study, the respiratory tidal volume is determined by another person not present in the study, and then the appropriate dose of remifentanyl is prescribed to cause hypotension. The researcher is not aware of the difference in respiratory tidal volume in two groups. In addition, the patient, the person recording the clinical and basic information of 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

Isfahan

Postal code

8179964167

Approval date

2023-03-29, 1402/01/09

Ethics committee reference number

IR.MUI.MED.REC.1402.011

Health conditions studied**1****Description of health condition studied**

Rhinoplasty

ICD-10 code

J34

ICD-10 code description

Other and unspecified disorders of nose and nasal sinuses

Primary outcomes**1****Description**

Blood pressure

Timepoint

Before surgery, immediately before anesthesia and every 10 minutes during surgery until the end of surgery

Method of measurement

Monitoring device

2**Description**

Blood pressure

Timepoint

Before surgery, immediately before anesthesia and every 10 minutes during surgery until the end of surgery

Method of measurement
Monitoring device

3

Description
Satisfaction

Timepoint
End of surgery

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In this group, the minimum tidal volume is selected based on the ideal weight (6 cc/kg). Then remifentanyl (according to routine) is given to cause hypotension and the appropriate dose is determined according to the patient's average blood pressure based on ideal body weight.

Category
Treatment - Drugs

2

Description
The second intervention group: In this group, the maximum current volume is selected based on the ideal weight (10cc/kg). Then remifentanyl (according to routine) is given to cause hypotension and the appropriate dose is determined according to the patient's average blood pressure based on ideal body weight.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Alireza Hoghooghi

Street address
Soffe Blvd, Isfahan

City
Isfahan

Province
Isfahan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
alireza.hoghooghi@gmail.com

2

Recruitment center
Name of recruitment center
Kashani Hospital

Full name of responsible person
Alireza Hoghooghi

Street address
Kashani street, Isfahan

City
Isfahan

Province
Isfahan

Postal code
8183983434

Phone
+98 31 3233 0091

Email
alireza.hoghooghi@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
Isfahan

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
Alireza Hoghooghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.hoghooghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Alireza Hoghooghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan

Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.hoghooghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Damanpak rizi
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
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
mahda.damanpak@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