Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim
Determining the effect of respiratory tidal volume on the required dose of remifentanil 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 remifentanil. 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 remifentanil (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 remifentanil (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 remifentanil to create controlled hypotension in rhinoplasty surgery

Public title
Effect of respiratory tidal volume on the required dose of remifentanil 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 remifentanil 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
Isfehan
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 remifentanil (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 remifentanil (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

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Postal code

8174675731

Phone

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Email

alireza.hoghooghy@gmail.com

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Alireza Hoghooghi

Street address

Kashani street, Isfahan

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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.

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Position

Non-faculty specialist doctor

Latest degree

Specialist

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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