

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparative evaluation of pressure control ventilation and volume control ventilation on intraoperative blood loss in rhinoplasty surgery .

#### Protocol summary

##### Study aim

Comparative evaluation of pressure control ventilation and volume control ventilation on intraoperative blood loss in rhinoplasty surgery

##### Design

This study is a double-blind randomized clinical trial with parallel groups on 30 patients. Block randomization method is used for randomization.

##### Settings and conduct

First a suitable venous line is taken and the infusion of venous fluids is started, then for premedication, midazolam 20 micrograms per kilogram and fentanyl 3 micrograms per kilogram are prescribed. Induction of anesthesia is performed in the same way in both groups. Patients are intubated with a spiral tube and subjected to mechanical ventilation. In the group of patients under mechanical ventilation with volume ventilation mode, the tidal volume is 7 ml per kg and the number of breaths is 10 times per minute and the ratio of inhalation to exhalation is 1: 2. In the pressure ventilation group with pressure mode, patients are exposed to a respiratory pressure of 15 cm of water and 10 breaths per minute, and gradually the pressure changes to reach EtCO<sub>2</sub> = 40-35. All patients are operated on by a surgeon. Comparison indicators are then recorded and measured. This study is performed in Rasoul Akram Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patient satisfaction; candidate for rhinoplasty surgery. Exclusion criteria: body mass index higher than 35; coagulation disorders.

##### Intervention groups

Intervention group: patients undergoing rhinoplasty surgery who, after anesthesia, use volume mode to give respiratory volume to the patient. Control group: patients undergoing rhinoplasty surgery who, after anesthesia, use pressure mode to give respiratory volume to the patient.

##### Main outcome variables

Surgeon satisfaction; bleeding; blood pressure; heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101026005026N13**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **prospective**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

##### Registration date

2022-01-30, 1400/11/10

##### Registrant information

##### Name

Masood Mohseni

##### Name of organization / entity

Rasul Akram hospital, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2326

##### Email address

mohseni@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative evaluation of pressure control ventilation and volume control ventilation on intraoperative blood loss in rhinoplasty surgery .

**Public title**

The effect of respiratory system on reducing bleeding in rhinoplasty surgery.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient satisfaction Candidate for rhinoplasty surgery

**Exclusion criteria:**

Pregnancy Body mass index higher than 35 Coagulation disorders

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, people who are responsible for patient care and analysis of outcomes do not know about the treatment process and study groups, and information is provided to them in groups A and B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway next to Milad Tower, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2021-11-30, 1400/09/09

**Ethics committee reference number**

IR.IUMS.FMD.REC.1400.517

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

Rhinoplasty

**ICD-10 code**

Y81

**ICD-10 code description**

General- and plastic-surgery devices associated with adverse incidents

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

Bleeding rate

**Timepoint**

During the surgery

**Method of measurement**

Number of blood gases and volume of blood inside the suction

**2****Description**

Surgeon satisfaction

**Timepoint**

During the surgery

**Method of measurement**

Using the Likert scale

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

During surgery

#### Method of measurement

Using monitor

### 2

#### Description

Heart rate

#### Timepoint

During surgery

#### Method of measurement

Using monitor

## Intervention groups

### 1

#### Description

Intervention group: First, a suitable venous line is taken and then premedication is prescribed. Induction of anesthesia of patients is performed by the same method in both groups. Then, the patients are intubated with a spiral tube made by Jahan Tajhiz Hakim Company and subjected to mechanical ventilation. In the intervention group, patients are mechanically ventilated with a volume ventilation mode with a current volume of 7 ml per kg and a rate of respiration of 10 per minute and a ratio of inhalation to exhalation of 1: 2. All patients are operated on by a surgeon. During surgery, the patient's bleeding rate was checked by checking the number of blood-soaked gases and the content of the suction, the surgeon's satisfaction was measured using the Likert scale, and the bleeding in the surgical field was measured using the Boezaart criterion at the end of the operation. The anesthesia device used for respiratory ventilation is the Fabius plus SW 3.n model.

#### Category

Treatment - Devices

### 2

#### Description

Control group: First, a suitable venous line is taken and then premedication is prescribed. Induction of anesthesia of patients is performed by the same method in both groups. Then, the patients are intubated with a spiral tube made by Jahan Tajhiz Hakim Company and subjected to mechanical ventilation. In the pressure ventilation group with pressure mode, patients are exposed to a respiratory pressure of 15 cm of water and 10 breaths per minute, and gradually the pressure changes to reach EtCO<sub>2</sub> = 40-35. All patients are operated on by a surgeon. During surgery, the patient's bleeding rate was checked by checking the number of blood-soaked gases and the content of the suction, the

surgeon's satisfaction was measured using the Likert scale, and the bleeding in the surgical field was measured using the Boezaart criterion at the end of the operation. The anesthesia device used for respiratory ventilation is the Fabius plus SW 3.n model.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Hospital

##### Full name of responsible person

Masood Mohseni

##### Street address

Rasul Akram hospital, Niayesh Ave, Sattarkhan St

##### City

Tehran

##### Province

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##### Postal code

1445613131

##### Phone

+98 21 6435 2326

##### Email

mohseni@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hosein Keyvani

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##### City

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##### Phone

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##### Email

keyvani.h@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Masood Mohseni  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be 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