Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

Comprative 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 EtCO2 = 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
Comprative 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 EtCO2 = 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
Tehran
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
Street address
Iran University of Medical Sciences, Hemmat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 5503
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

Street address

Rasul Akram hospital, Niayesh Ave, Sattarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2326

Email

mohseni@med.mui.ac.ir

Person responsible for scientific 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

Street address

Rasul Akram hospital, Niayesh Ave, Sattarkhan St

City

Tehran

Province

Tehran

Postal code

1446513131

Phone

+98 21 6435 2326

Email

mohseni@med.mui.ac.ir

Person responsible for updating data

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

Street address

Rasul Akram hospital, Niayesh Ave, Sattarkhan St

City

Tehran

Province

Tehran

Postal code

1446513131

Phone

+98 21 6435 2326

Email

mohseni@med.mui.ac.ir

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