Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Influence of Positive End-Expiratory Pressure on Intraoperative Bleeding and respiratory parameters in Rhinoplasty

Protocol summary

Study aim
Determining the effect of PEEP (Positive End-Expiratory Pressure)on the amount of bleeding and respiratory components in patients undergoing rhinoplasty

Design
In this study, 68 patients undergoing rhinoplasty were randomly assigned to two equal groups using random generator program and the patients code is packed in packets with letters A and B.

Settings and conduct
Participants and outcome evaluators are blind in this study. During surgery, patients receive PEEP 5 or zero depending on their contents.

Participants/Inclusion and exclusion criteria
18 to 40 years old patients referred to Amir-Al-Momenin hospital for Rhinoplasty in 1396 are participate in this study and patients that use anticoagulative drugs and Aspirin or alcohol and substance abusers and allergic patients to anesthetics drugs and patients with coronary heart or pulmonary diseases are excluded.

Intervention groups
1- patients receive 5CmH2o PEEP 2- patients receive no PEEP

Main outcome variables
amount of bleeding and respiratory Components

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140310016917N4**
Registration date: **2018-01-01, 1396/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-01, 1396/10/11**
Update count: **0**

Registration date
2018-01-01, 1396/10/11

Registrant information

Name
Ali Ashraf

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 13 1321 0434

Email address
aliashraf@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-30, 1396/10/09

Expected recruitment end date
2018-01-29, 1396/11/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Influence of Positive End-Expiratory Pressure on Intraoperative Bleeding and respiratory parameters in Rhinoplasty

Public title
The Influence of Positive End-Expiratory Pressure in Rhinoplasty

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
18 to 40 years old patients patients referred to Amir-Al-

Momenin hospital for Rhinoplasty in 1396

Exclusion criteria:

use of anticoagulative drugs and Aspirin alcohol and substance abuse allergic to anesthetics drugs coronary heart or pulmonary diseases

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned random sequences using the Random Generator program to the two groups and are packed in packets with letters A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

After random division, the names are in the envelopes packed with letters A and B. Assignment of patients is based on sequences determined by the technician. study is Double-blind by patients and outcome evaluator.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan university of Medical Sciences

Street address

Namjoo Street

City

Rasht

Province

Guilan

Postal code

4193893345

Approval date

2017-12-23, 1396/10/02

Ethics committee reference number

IR.GUMS.REC.1395.400

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Volume of soaked blood

Timepoint

At the end of operation

Method of measurement

Suction machine

2

Description

Weight of sterile gases

Timepoint

At the end of operation

Method of measurement

Weighing scale

Secondary outcomes

1

Description

Respiratory components

Timepoint

Initiation , every 30 minutes and at the end of operation

Method of measurement

Anesthesia machine

Intervention groups

1

Description

Control group: No Positive End-Expiratory Pressure (PEEP) during surgery

Category

Prevention

2

Description

Intervention group: PEEP 5 CmH2O

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir-al-Momenin Hospital

Full name of responsible person
Ali Ashraf

Street address
17- Shahrivar Street

City
Rasht

Province
Guilan

Postal code
4193893345

Phone
+98 13 3322 5242

Email
Draliashraf@yahoo.fr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Shadman Nemati

Street address
Namjoo Street

City
Rasht

Province
Guilan

Postal code
4193893345

Phone
+98 13 3333 6394

Email
Nemati@gums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Ali Ashraf

Position
Anesthesiologist/ Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Namjoo Street

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 1321 0434

Fax
+98 13 1324 5132

Email
Draliashraf@yahoo.fr

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Ali Ashraf

Position
Anesthesiologist/ Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Namjoo Street

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3334 4812

Email
Draliashraf@yahoo.fr

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Ali Ashraf

Position
Anesthesiologist/ Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Street address
Namjoo Street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 1321 0434
Fax
+98 13 1324 5132
Email
aliashraf@gums.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
Yes - There is 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
Title and more details about the data/document
The final outcome of the study will be shared
When the data will become available and for how long
6 months after publish
To whom data/document is available
academic Researchers
Under which criteria data/document could be used
after sharing data and outcomes there is no limits for use.
From where data/document is obtainable
Dr Ali Ashraf draliashraf@yahoo.fr
What processes are involved for a request to access data/document
contact by email
Comments