

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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

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17- Shahrivar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

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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

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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

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