Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of nasal packing at night before surgery on patient agitation after rhinoplasty

Protocol summary

Study aim
The effect of nasal packing at night before surgery on patient agitation after rhinoplasty
Design
Clinical trial, single-blind, has a control group, parallel, randomized
Settings and conduct
Patients will be divided into two groups: control and intervention. The intervention group will be blocked by the plastic cap on the night before the rhinoplasty is performed for one hour and will only breathe through the mouth. Patients in the control group will not receive any action.
Participants/Inclusion and exclusion criteria
Entry criteria: ASA Class 1 and 2, and BMI less than 30
Exit criteria: Smoking
Intervention groups
The intervention group will be blocked by the plastic cap on the night before the rhinoplasty is performed for one hour and will only breathe through the mouth.
Main outcome variables
Agitation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190325043107N1**
Registration date: **2019-03-30, 1398/01/10**
Registration timing: **prospective**

Last update: **2019-03-30, 1398/01/10**
Update count: **0**
Registration date
2019-03-30, 1398/01/10

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-20, 1398/02/30
Expected recruitment end date
2019-06-20, 1398/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of nasal packing at night before surgery on patient agitation after rhinoplasty

Public title
The effect of nasal packing on patient agitation after rhinoplasty
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
ASA Class 1 and 2 BMI below 30
Exclusion criteria:
Smoking
Age
No age limit
Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are simply randomized to two groups , through random number table; received a special code and are treated with own group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
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5165665631
Approval date
2019-01-07, 1397/10/17
Ethics committee reference number
IR.TBZMED.REC.1397.827

Health conditions studied

1

Description of health condition studied
Agitation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Agitation
Timepoint
5 minutes for 45 minutes
Method of measurement
Riker Sedation Agitation Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For one hour before the night of rhinoplasty, nasal holes will be blocked by plastic clips and breathing will be done through the mouth.
Category
Treatment - Devices

2

Description
Control group: There will be no work for this group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
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Sponsors / Funding sources

1

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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
Tabriz 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
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Associate professor
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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