

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### 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

##### Postal code

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

##### Full name of responsible person

Mahmoud Eydi

##### Street address

Imam Reza Hospital, Azadi Ave

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

6165665631

##### Phone

+98 21 3335 5921

##### Email

mkhanbabayi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Abolghasem Jouyban

##### Street address

Imam Reza Hospital, Azadi Ave

##### City

Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665631  
**Phone**  
+98 41 3335 7310  
**Email**  
Ajouyban@hotmail.com  
**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

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mahmoud Eydi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Imam Reza Hospital, Azadi Ave  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665631  
**Phone**  
+98 41 3335 7310  
**Email**  
Mkhanbabayi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mahmoud Eydi

**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Imam Reza Hospital, Azadi Ave  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665631  
**Phone**  
+98 41 3335 7310  
**Email**  
Mkhanbabayi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mehdi Khanbabayi Gol  
**Position**  
MSc in Nursing Education  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Imam Reza Hospital, Azadi Ave  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665631  
**Phone**  
+98 41 3334 7054  
**Fax**  
**Email**  
Khanbabayimehdi69@gmail.com

## 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