

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluating the effect of oral Gabapentin premedication upon bleeding and hemodynamic changes due to direct laryngoscopy and endotracheal intubation in patients candidate for septorhinoplasty surgery

#### Protocol summary

##### Summary

This study is to assess the premedication effect of oral Gabapentin on bleeding and hemodynamic variations due to direct laryngoscopy and endotracheal intubation in patients' candidate for septorhinoplasty surgery. This study performed on 100 patients 18-45 years old with ASA class I, II who are candidate for septorhinoplasty. Patients with any history of hypertension, morbid obesity, heart failure, hepatic, renal or endocrine disorders do not enter in this study and In the event of medical complications are excluded. The patients will be randomly divided into 2 groups: Group G takes 900 mg oral Gabapentin (300 mg oral Gabapentin capsules 3 times a day) Single daily dose with 20 ml water, two hours before operation. Group P takes the same amount of placebo at the same time. This is a double blinded clinical trial study. In the operation room the patient are monitored for ECG(Electrocardiography), spO2 (Oxygen saturation), Non Invasive Blood Pressure (NIBP), End-tidal carbon dioxide (ETCO2) and the basic amounts of Heart rate (HR), Systolic Blood Pressure (SBP) , Diastolic Blood Pressure (DBP), Mean Arterial Pressure ( MAP) and spO2 are recorded. The result of this study is to reduce bleeding.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201409288677N3**  
Registration date: **2014-12-01, 1393/09/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-01, 1393/09/10

#### Registrant information

##### Name

Farnoush Farzi

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 5624

##### Email address

farnoush\_farzi@gums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Guilan University of Medical Sciences

#### Expected recruitment start date

2014-11-01, 1393/08/10

#### Expected recruitment end date

2015-03-01, 1393/12/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluating the effect of oral Gabapentin premedication upon bleeding and hemodynamic changes due to direct laryngoscopy and endotracheal intubation in patients candidate for septorhinoplasty surgery

#### Public title

The effect of oral Gabapentin premedication upon bleeding and hemodynamic changes due to direct laryngoscopy

#### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 45 years old; American Society of Anesthesiologists (ASA) I,II; Candidate for Septorinoplasty  
Exclusion criteria: Drug Side effects; Patients refuse treatment

### Age

From **18 years** old to **45 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

random blocks

## 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

##### Postal code

4193893345

#### Approval date

2014-08-19, 1393/05/28

#### Ethics committee reference number

1930231623

## Health conditions studied

### 1

#### Description of health condition studied

Bleeding

#### ICD-10 code

J34.8

#### ICD-10 code description

Other specified disorders of nose and nasal sinuses

## Primary outcomes

### 1

#### Description

Heart Rate

#### Timepoint

Upon arrival to operating room,3 ,5 ,10 ,15 minutes after endotracheal intubation and 10 minutes after extubation

#### Method of measurement

Beats per minute (bpm) by Saadat monitoring system

### 2

#### Description

Systolic Blood Pressure

#### Timepoint

Upon arrival to operating room,3 ,5 ,10 ,15 minutes after endotracheal intubation and 10 minutes after extubation

#### Method of measurement

mmHg by Saadat monitoring system

### 3

#### Description

Amount of intra operative bleeding

#### Timepoint

At the end of the operation

#### Method of measurement

mL/According to the blood volume in the suction, by minus volume of physiological saline solution that added due to washing , plus 15 for each blood gaus

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention 1) 900 mg (3x300 mg capsules) Gabapentin made by Iran Darou industries is taken single daily dose with 20 ml water, 2 hours before operation

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2) Three capsules looking exactly like Gabapentin capsule including placebo which is made by the same industry is taken by the patient 2 hours before surgery

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Amir AlMomenin Hospital

**Full name of responsible person**

Farnoush Farzi

**Street address**

Namjoo Street

**City**

Rasht

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Guilan University of Medical Sciences

**Full name of responsible person**

Abtin Heidarzadeh

**Street address**

Shahid beheshti Highway

**City**

Rasht

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Guilan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Farnoush Farzi

**Position**

Anesthesiologist/ Assistant Professor

**Other areas of specialty/work**

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*