

# 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*