Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of oral Gabapentin premedication upon bleeding and hemodynamic changes due to direct laryngoscopy and endotracheal intubation in patients candidate for septorinoplasty 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 septorinoplasty surgery. This study performed on 100 patients 18-45 years old with ASA class I, II who are candidate for septorinoplasty. 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

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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 septorinoplasty 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 intubatioin 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 intubatioin 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 (3×300 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
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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

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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