

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Summary

This double-blind randomized clinical trial on 100 patients with class 1 and 2 Anesthesiology admitted to hospitals of Babol University of Medical Sciences through easy sampling divided into two equal groups and alternate is performed after informed consent from patients Consciously. Inclusion criteria: elective orthopedic surgery; the patients ranged from 18 to 65 years; BMI (Body Mass Index) of less than 30 kg/m<sup>2</sup> and a maximum of 2 hours of surgery time. Exclusion criteria: history of seizures; diabetes, Parkinson , motion sickness and migraine; psychotropic substances or sedatives drugs; addiction to alcohol or opoide; blood transfusion and that products; administration of vasoactive drugs during anesthesia; existence of active infection before anesthesia; receive any anti vomiting 48 hours preoperative; intra operative use of propofol; systolic blood pressure less than 90 or greater than 160 mmHg and patients with difficult intubation and body temperature less than 36 or more than 37.5 degrees centigrade. To a group of patients, will be a tablet 0/2 mg Clonidine with 50 ml of water and after 60 minutes will be induction of anesthesia. In the second group will administer Granisetron 40 mcg / kg intravenous immediately before induction of anesthesia and premedication, Induction and maintenance of anesthesia in both groups will be with the same conditions. Routine monitoring is utilized during anesthesia. Vital signs will be controlled at various intervals. Nausea, vomiting and shivering will be assessed and record based on criteria of measurement and the results are derived based on data analysis.

Last update:

Update count: **0**

#### Registration date

2012-06-23, 1391/04/03

#### Registrant information

##### Name

Ommelaila Rabiee Kenari

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1223 4274

##### Email address

syasin36@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

Babol University of Medical Sciences

#### Expected recruitment start date

2012-06-21, 1391/04/01

#### Expected recruitment end date

2012-12-21, 1391/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205089684N1**

Registration date: **2012-06-23, 1391/04/03**

#### Scientific title

The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

#### Public title

The comparison of Clonidine and Granisetron in the prevention of postoperative shivering, nausea and vomiting.

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: elective orthopedic surgery, the patients' age ranged from 18 to 65 years old; BMI (Body Mass Index) less than 30 kg/m<sup>2</sup> and a maximum of 2 hours of surgery time. Exclusion criteria: emergency surgery; history of seizures, diabetes, Parkinson's or any other diseases that can cause shivering; motion sickness and migraine; history of psychotropic substances or sedatives drugs; addiction to alcohol or opioide; blood transfusion and that products, administration of vasoactive drugs during anesthesia; existence of active infection before anesthesia; receive any anti vomiting 48 hours preoperative; intra operative use of propofol; systolic blood pressure less than 90 or greater than 160 mmHg; patients with difficult intubation and body temperature less than 36 or more than 37.5 degrees centigrade

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

2

### **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**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Babol University of Medical Sciences

##### **Street address**

Babol. gangafroz state .University of Medical Sciences  
babol

##### **City**

Babol

##### **Postal code**

47176

### **Approval date**

2012-04-24, 1391/02/05

### **Ethics committee reference number**

6266

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

General anesthesia

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

Nausea and vomiting

#### **Timepoint**

During recovery and world at the 6 hours

#### **Method of measurement**

The patients are assessed of the incidence of nausea and vomiting, by a trained individual which is not aware to administrate any drug, and then items to be recorded. Nausea will be assess and recorded base on feeling with the scale of a Multiple Choice without nausea, moderate and severe nausea. If patient can feel nausea at least 5 minutes it is considered an episode of nausea. The severe vomiting will be recorded base on without vomiting, once vomiting (mild), two or three occasions vomiting (moderate) and more than three times vomiting (severe). If there was between vomiting an interspaced at least one minute, each one of them is considered on episode vomiting. Meanwhile, retching can be considered equivalent to vomiting. In items that, patients had a severe nausea or twice vomiting and or the patient's own requests, are prescribed 8 mg Intravenous Metoclopramide as anti-nausea drugs supplemental.

### **2**

#### **Description**

shivering

#### **Timepoint**

The end of anesthesia and during recovery

#### **Method of measurement**

The shivering of patients will be evaluated after end anesthesia and during recovery with visual assessment scale, including: Zero =the cases without shivering, degree 1 = status of vasoconstriction and peripheral cyanosis without other cause (or straight hair, but without visible muscular activity), degree 2 = visible muscular activity confined to one muscle group (or mild fasciculation face and neck), degree 3= Visible, Shivering in more than one group of muscle, degree 4= Muscle activity visible that include all body. The items by a person trained and experienced and without the knowledge of the prescribed medicines will be assessed and are recorded in the relevant information. If grade of shivering was 3 or 4, the patient is treated with 25 mg

intravenous pethidine.

## Secondary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled.

#### Method of measurement

Sphygmomanometer

### 2

#### Description

Core temperature (Tempan)

#### Timepoint

Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled

#### Method of measurement

Thermometer Tempanic

### 3

#### Description

Diastolic blood pressure

#### Timepoint

Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled.

#### Method of measurement

Sphygmomanometer

### 4

#### Description

Surface temperature (axillary)

#### Timepoint

Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled

#### Method of measurement

Thermometer's Axillary

### 5

#### Description

Heart rate

#### Timepoint

Variables of vital signs at intervals before, 10 and 20 minutes after drug administration and immediately after transfer to the recovery are controlled

#### Method of measurement

Pulsoxymetri

## Intervention groups

### 1

#### Description

Intervention group: Administration of Granisetron 40 mcg/kg intravenous immediately before induction of General Anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Control group:A tablet 0.2 mg clonidine with 50 ml of water will be administered and performed induction of general anesthesia after 60 minutes.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

shahid Beheshti Hospital, Babol

##### Full name of responsible person

Doctor Ebrahim Alijanpour

##### Street address

Babol,Keshvari state

##### City

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr. Amrolah Mostafazadeh (Research Assistant)

##### Street address

Babol. Gangafroz,s state.

##### City

Babol

##### Grant name

49

##### Grant code / Reference number

1033

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

Yes

##### Title of funding source

Babol 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**  
Research Assistant of Babol University of Medical Sciences  
**Full name of responsible person**  
Ommelaila Rabiee  
**Position**  
MS / faculty  
**Other areas of specialty/work**  
**Street address**  
University of Medical Sciences Babol - Paramedical Sciences  
**City**  
babol  
**Postal code**  
47176  
**Phone**  
+98 11 1223 4274  
**Fax**  
+98 22 34367  
**Email**  
syasin36@yahoo.com - ol.rabiee@gmail.com - amir.9632@gmail.com  
**Web page address**  
www.mubabol.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Research Assistant of babol University of Medical Sciences  
**Full name of responsible person**  
Doctor Ebrahim Alijanpour  
**Position**  
Anesthesiologist  
**Other areas of specialty/work**  
**Street address**  
Babol. Gangaafroz state. Rohani Hospital. Department of Anesthesiology  
**City**  
Babol  
**Postal code**  
47176

**Phone**  
+98 112238296  
**Fax**  
+98 22 34651  
**Email**  
dralijanpour@yahoo.com  
**Web page address**  
www.mubabol.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Research Assistant of babol University of Medical Sciences  
**Full name of responsible person**  
Ommelaila Rabiee  
**Position**  
MS/faculty  
**Other areas of specialty/work**  
**Street address**  
Babol. Gangaafroz state. University of Medical Sciences Babol  
**City**  
Babol  
**Postal code**  
47176  
**Phone**  
+98 11 1223 4274  
**Fax**  
+98 22 34367  
**Email**  
syasin36@yahoo.com - ol.rabiee@gmail.com - amir.9632@gmail.com  
**Web page address**  
www.mubabol.ac.ir

## 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*