

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Efficacy of oral tizanidine for postoperative pain in perianal surgery.

#### Protocol summary

##### Summary

The purpose of this study was to evaluate the efficacy of oral tizanidine in preventing pain and meperidine consumption during perianal surgery under spinal anesthesia. 60 male patients scheduled for anorectal surgery under spinal anesthesia were enrolled in this study. Patients were randomized into two groups of case and control. The case group received 4mg tizanidine and the control group received placebo 1 hour before surgery. VAS and meperidine consumption and side effects were recorded during the anesthesia and for 24 hours.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201210315381N3**

Registration date: **2012-12-23, 1391/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-23, 1391/10/03

##### Registrant information

###### Name

Nadia Banihashem

###### Name of organization / entity

Babol University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 22 38296

###### Email address

nbanihashem@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice-chancellor Of Research Babol University Of Medical Science

##### Expected recruitment start date

2012-07-31, 1391/05/10

##### Expected recruitment end date

2012-11-20, 1391/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of oral tizanidine for postoperative pain in perianal surgery.

##### Public title

Efficacy of oral tizanidine for postoperative pain in perianal surgery.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

The inclusion criteria :patients of candidate of perianal surgery; males; ASA I-II; elective surgery; 20-55 years  
exclusion criteria: ,psychology disorder; addiction; history of allergy; history of hypertension; drug history of clonidine and tizanidine; surgery duration longer than 2 hours.

##### Age

From **20 years** old to **55 years** old

##### Gender

Male

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **60**

##### Randomization (investigator's opinion)

Randomized

### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

##### Placebo

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

Daneshgah Sq - Ganjafrooz Av

##### City

Babol

##### Postal code

##### Approval date

2012-07-30, 1391/05/09

##### Ethics committee reference number

6830/30/پ/ز

## Health conditions studied

### 1

#### Description of health condition studied

preanal surgery

#### ICD-10 code

k62.9

#### ICD-10 code description

disease of anus and rectum,unspecified

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

From the first hour after surgery for 24 hours, every 8 hour

#### Method of measurement

visul analoge scale

### 2

#### Description

meperidine consumption

#### Timepoint

24 hours

#### Method of measurement

meperidine consumption(mg)

## Secondary outcomes

### 1

#### Description

Patient's hemodynamics

#### Timepoint

24 hours after surgery

#### Method of measurement

Blood pressure and heart rate were evaluated by digital monitoring devices.

### 2

#### Description

nausea, vomiting

#### Timepoint

24 hours

#### Method of measurement

Through a questionnaire and observation

## Intervention groups

### 1

#### Description

intervention:tizanidine,4 mg,one hour before surgery.

#### Category

Treatment - Drugs

### 2

#### Description

control:plasebo,one hour before surgery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Behshti Hospital

##### Full name of responsible person

Dr Mohammad Ali Roupani

##### Street address

##### City

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

##### Full name of responsible person

Dr Amrolah Mostafazadeh

**Street address**

Vice-chancellor Of Research, Daneshgah Square,  
Ganjafrooz Avenue

**City**

Babol

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellor Of Research 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**

Babol University Of Medical Sciences

**Full name of responsible person**

dr nadia banihashem

**Position**

Assistant Professor Of Anesthesiology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Dr Mohammad Ali Roupani

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Assistant Professor Of Anesthesiology

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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*