

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effects of preoperative administration of oral pregabalin on postoperative pain after abdominal surgeries

#### Protocol summary

##### Summary

The purpose of this study was to evaluate the effects of preoperative administration of oral pregabalin on postoperative pain after surgery in the patients undergoing general anesthesia for abdominal surgeries in Shahid Sadoughi hospital in Yazd, Iran. In this randomized double blind trial, 60 patients, aged 40-60 years old, and ASA physical status I and II, were assigned into one of the following two groups to receive pregabalin, 300 milligram 2 hours before surgery, orally in the intervention group or placebo in the control group. Intravenous pump with 20 mg morphine in 100 ml normal saline was used as the analgesic method postoperatively and the patients received morphine as bolus doses according to their requests. Pain was assessed through visual analog scale (VAS) at 2, 6, 12, and 24 hours after the surgery. In addition, the first request of the patient for analgesia, the amount of morphine consumed, and side effects of gabapentin (dizziness, blurred vision, ataxia, nausea, vomiting) were evaluated during 24 hours and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201408272963N19**

Registration date: **2014-12-26, 1393/10/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-26, 1393/10/05

##### Registrant information

Name

Shekoufeh Behdad

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1822 1386

##### Email address

drbehdad@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of preoperative administration of oral pregabalin on postoperative pain after abdominal surgeries

##### Public title

Evaluation of the effects of preoperative administration of oral pregabalin on postoperative pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: women with American Society of Anesthesia (ASA) physical status I or II who are candidate for elective abdominal surgery, age 40-60 years old, BMI < 35. Exclusion criteria: Anaphylaxis reaction to the anesthetic drugs, duration of the operation longer than 2

hours  
**Age**  
From **40 years** old to **65 years** old  
**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
N/A

**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**

دانشگاه شهید صدوقی

**Street address**

میدان باهنر

**City**

یزد

**Postal code**

**Approval date**

2014-09-10, 1393/06/19

**Ethics committee reference number**

9630

## Health conditions studied

### 1

**Description of health condition studied**

pregabalin

**ICD-10 code**

Y46.6

**ICD-10 code description**

Other and unspecified antiepileptics

## Primary outcomes

### 1

**Description**

postoperative pain

**Timepoint**

2,6,12,24 hours postoperatively

**Method of measurement**

visual analog pain score

## Secondary outcomes

### 1

**Description**

side effects of pregabalin (dizziness, blurred vision, ataxia, nausea, vomiting)

**Timepoint**

2, 6, 12 and 24 hours after operation

**Method of measurement**

asking the patient, physical examination

## Intervention groups

### 1

**Description**

pregabalin 300 mg orally 2 hours before surgery

**Category**

Treatment - Drugs

### 2

**Description**

placebo at the same time

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Sadoughi Hospital

**Full name of responsible person**

Dr. Shekoufeh Behdad

**Street address**

Shahid Sadoughi Hospital, Ebnesina Blv, Yazd, Iran

**City**

Yazd

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr. Hasan Mozaffari

**Street address**

Bahonar square

**City**

Yazd

**Grant name**

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Sadoughi 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**  
Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Dr. Shekoufeh Behdad  
**Position**  
Associate Professor  
**Other areas of specialty/work**  
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+98 35 3822 4104  
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**Email**  
behdad90@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

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associate professor

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## Person responsible for updating data

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**Position**  
Associate professor  
**Other areas of specialty/work**  
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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*