

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### To detect the efficacy of oral gabapentin on pain intensity in patients with acute low back pain patients

#### Protocol summary

##### Summary

This study aimed to evaluate the efficacy of oral gabapentine on pain intensity in patients with low back pain. This research is an interventional single-blind clinical trial study. 100 patients with acute low back pain, mild to moderate (less than 4 weeks) with age between 20 to 50 years attending clinics affiliated with the Shahrekord University of Medical Sciences by convenience sampling are divided in two identical groups, intervention and control groups. Both groups are treated two weeks using naproxen tablets(500mg) two times in a day. In group 1, it is received gabapentine 100 mg 2 tablets daily, in group 2, placebo pills is prescribed. Patient characteristics in both groups including: demographic data, pain scores based on the Visual Analog Scale and patient performance including quality of public activity, mood, walking ability, social activities and sleep are recorded before the start of the study and on treatment days 8,15 30.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303096480N4**

Registration date: **2013-04-20, 1392/01/31**

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

Last update:

Update count: **0**

##### Registration date

2013-04-20, 1392/01/31

##### Registrant information

##### Name

Mohammad Taghi Moradi

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1334 9509

##### Email address

mtmoradi@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research Affairs, Shahrekord University of Medical Sciences

##### Expected recruitment start date

2013-03-15, 1391/12/25

##### Expected recruitment end date

2013-05-22, 1392/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To detect the efficacy of oral gabapentin on pain intensity in patients with acute low back pain patients

##### Public title

Efficacy of oral gabapentin on pain intensity in patients with acute low back pain patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. No systematic disease (diabetes or thyroid disease); infectious diseases(brucellosis and tuberculosis); vascular disease; clotting disorder(hemophilia); structural disorders ( scoliosis and Spondylolysthesis). 2. The neurologic symptoms (positive SLR, cross SLR, loss of tendon reflexes and sensation. 3. Aged between 20-24 years 4. Complained of acute pain (less than 4 weeks). 5. Patients' willingness to participate

in the study . Exclusion criteria : 1-Corticosteroid injections in the back region or other parts of the body in the 3 months before the study and during the study. 2- No satisfaction to continue treatment. 3-Individuals who consume narcotic drugs 4- The history of recurring back pain for more than 4 times in a year. 5- Consumption multiple medications for other diseases sleep medications, relaxant, acetaminophen and NSAIDs).

#### **Age**

From **20 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

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)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

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

Shahrekord University of Medical Sciences

###### **Street address**

Kashani Blvd, Secretary of Shahrekord University of Medical Sciences, Deputy of Research Affairs

###### **City**

Shahrekord

###### **Postal code**

###### **Approval date**

2012-01-13, 1390/10/23

###### **Ethics committee reference number**

90-2-13

### **Health conditions studied**

#### **1**

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

acute back pain

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

M54.5

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

Low back pain

### **Primary outcomes**

#### **1**

##### **Description**

Pain

##### **Timepoint**

Before intervention, 15th, 8th, 30th day after intervention

##### **Method of measurement**

VAS standard Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Control group: Two weeks undertreatment by Naproxen tablets(500mg) twice each day and placebo daily two tabs

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Interventional group: Two weeks undertreatment by Naproxen tablets(500mg)twice each day and Gabapentin(100mg) daily two talets

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Hospital Clinic of Ayatallah Kashani

###### **Full name of responsible person**

Dr Morteza Dehghan

###### **Street address**

Shariati Street

###### **City**

Shahrekord

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Vice chancellor for research, Shahrekord University of Medical Sciences

###### **Full name of responsible person**

Mahmoud Mobasheri

**Street address**

Kashani Blvd

**City**

Shahrekord

**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, Shahrekord 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**

Shahrekord University OF Medical Sciences

**Full name of responsible person**

Dr Morteza Dehghan

**Position**

Assistant Professor in Orthopedic Department

**Other areas of specialty/work****Street address**

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**City**

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Shahrekord university of Medical Sciences

**Full name of responsible person**

Dr Morteza Dehghan

**Position**

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**Other areas of specialty/work****Street address**

Ayatallah Kashani Hospital

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**Web page address****Person responsible for updating data****Contact****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*