Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity

Shahrekord University of Medical Sciences

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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-INividuals 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, Secretery 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 Questionaire

Secondary outcomes

empty

Intervention groups

1

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

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 chancellory for research, Shahrekord University of Medical Sciences

Full name of responsible person
Mahmoud Mobasheri

Street address
Kashani Blvd
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Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellory 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
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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