

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of efficacy of sodium valproate low dose in cervical and lumbar radicular pain management and it's relation with pharmacokinetic properties

Protocol summary

Summary

In this double blind clinical trial study, 80 patients from men and women who are between 30-60 years old and their lumbar or cervical radicular pain were confirmed by rheumatology specialist were selected, and will be randomly allocated into 2 study groups: 40 will be received sodium valproate and celecoxib and a nonspecific analgesic acetaminophen as rescue medication, and 40 will be received placebo and celecoxib and acetaminophen. For determining pain intensity, a testimonial will be filled by patients Before starting treatment, then treatment starts in 10 days with sodium valproate 200 mg and placebo once daily. After 5 half life following initiation of therapy blood sample will be taken for determining mean through concentration. The method of analysis of drug plasma concentration is gas chromatography with flame ionization detector. After finishing therapy, another testimonial will be filled for final pain intensity and number of acetaminophen administration during past 10 days and evaluation of efficacy of sodium valproate on pain score by comparing visual analog scale before and after the therapy with controlling the group by T test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403101836N8**
Registration date: **2014-03-18, 1392/12/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-03-18, 1392/12/27

Registrant information

Name

Seyed Mojtaba Sohrevardi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-04-05, 1393/01/16

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of sodium valproate low dose in cervical and lumbar radicular pain management and it's relation with pharmacokinetic properties

Public title

Evaluation of efficacy of sodium valproate in cervical and lumbar radicular pain management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Diagnosis of lumbar or cervical

radicular pain based on diagnostic of rheumatology specialist. 2. Age between 30 and 60 years. 3. Patients will included if they don't have possibility of health risk or confounding by other diseases of syndromes, e.g., pregnancy, thyroid disorders, hepatic or kidney disorders, congestive heart failure and diabetes mellitus. 4. Patients havent used sodium valproate or if they have been using, they must remember pain intensity before using sodium valproate and can compare with current pain intensity. 5. Weight between 60 and 90 kg. Exclusion criteria: 1. Intolerance to sodium valproate side effects. 2. Patients will be forced to administered medicines that change protein binding or clearance of sodium valproate. 3. Patients will be given diseases that affect the results of study.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Shahid Sadoughi University of Medical Sciences

Street address

Faculty of Pharmacy- Shahid Sadoughi University of
Medical Sciences- Shohadaye Gornam boulevard-
Professor Hesabi boulevard- Yazd

City

Yazd

Postal code**Approval date**

2014-03-04, 1392/12/13

Ethics committee reference number

17/1/248644/پ

Health conditions studied**1****Description of health condition studied**

cervical and lumbar radicular pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain intensity

Timepoint

Before intervention, 10 days after beginning of
intervention

Method of measurement

Visual analog scale

2**Description**

Number of acetaminophen administration

Timepoint

10 days after beginning of intervention

Method of measurement

Empty acetaminophen blister which will be recieved by
patients

Secondary outcomes**1****Description**

Serum concentration of sodium valproate

Timepoint

10 days after beginning intervention

Method of measurement

Gas chromatography with flame ionization detector

Intervention groups**1****Description**

Control group: placebo

Category

Placebo

2**Description**

Intervention group: sodium valproate, 200 mg, once a
day for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital clinic

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Fatemeh Ezoddini Ardakani

Street address

Research Department, Building No 2, Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

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

Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Seyed Mojtaba Sohrevardi

Position

Doctorate of pharmacy, Phd of clinical pharmacy, research assistant of yazd faculty of pharmacy

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