Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 controling 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)

Phone

+98 34 1320 5001

Email address

smsohrevardi@kmu.ac.ir

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 administerated 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 Gomnam 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
Street address
Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences- Shohadaye Gomnam boulevard- Professor Hesabi boulevard- Yazd
City
Yazd
Postal code
Phone
+98 35 1820 3410
Fax
Email
smsohrevardi@ssu.ac.ir
Web page address

Person responsible for scientific 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
Street address
Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences- Shohadaye Gomnam boulevard- Professor Hesabi boulevard- Yazd
City
Yazd
Postal code
Phone
+98 35 1820 3410
Fax
Email
smsohrevardi@ssu.ac.ir; smsohrevardi@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences- Shohadaye Gomnam boulevard- Professor Hesabi boulevard- Yazd
City
Yazd
Postal code
Phone
+98 35 1820 3410
Fax
Email
smsohrevardi@ssu.ac.ir
Web page address

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