

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the efficacy and safety of pregabalin and carbamazepine in patients with postherpetic neuralgia

Protocol summary

Study aim

Evaluation of efficacy and safety of carbamazepine and pregabalin for patients with post-shingles pain

Design

Clinical trial with two intervention groups, with parallel groups, not blinded, phase 2 on 40 patients, randomized

Settings and conduct

The office of counseling and guidance professors (pain fellowship and neurologist) is the place of data collection. The tool used is a questionnaire. The severity of pain is recorded according to the VAS criteria at the beginning and end.

Participants/Inclusion and exclusion criteria

Inclusion criteria All patients over 18 years of age with a history of neuropathic pain after shingles for at least one month
Exclusion criteria Allergy to test drugs, pregnancy, seizures, serious psychiatric illness, use of drugs affecting neuropathic pain and pain other than neuropathic shingles

Intervention groups

a group of 150 mg of pregabalin daily and a group of 400 mg of carbamazepine for 4 weeks.

Main outcome variables

pain intensity based on the VAS scale drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210725051977N1**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

Name

Masoud Khoshbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 9893

Email address

masoudkhoshbin@iauyazd.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-11, 1400/07/19

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

2021-10-11, 1400/07/19

Actual recruitment end date

2021-11-21, 1400/08/30

Trial completion date

2021-11-22, 1400/09/01

Scientific title

Evaluation of the efficacy and safety of pregabalin and carbamazepine in patients with postherpetic neuralgia

Public title

Evaluation of efficacy and safety of pregabalin and carbamazepine in reducing pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 18
History of postherpetic neuralgia for at least 1 month

Exclusion criteria:

History of Allergy to carbamazepine or pregabalin
History of kidney or liver disease

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size of the study is 40 patients. The first patient who admitted to the office and meets the inclusion criteria will be No. 1 and the 40th patient will be No. 40. In advance, using the <https://www.random.org>, from the "List Randomizer" section of the website, the numbers 1 to 40 is randomly divided into two groups of 20 (the first twenty patients for the carbamazepine group and the second 20 patients for the pregabalin group). Example: Number 5 is in the pregabalin group in randomization of numbers 1 to 40, therefore, the fifth patient who meets the inclusion criteria will be in the pregabalin group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd Azad University Medical School

Street address

Safaieh, Alam Square, Ali Ibn Abitaleb Medical School

City

Yazd

Province

Yazd

Postal code

8915813135

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.IAU.YAZD.REC.1400.034

Health conditions studied

1

Description of health condition studied

Evaluation of the efficacy and safety of pregabalin and carbamazepine in patients with postherpetic neuralgia

ICD-10 code

B02.2

ICD-10 code description

Zoster with other nervous system involvement

Primary outcomes

1

Description

severity of post-herpetic neuralgia in each group

Timepoint

2, 5 and 8 weeks after starting the treatment

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

frequency of adverse drug complications in each group

Timepoint

2, 5 and 8 weeks after starting the drug, or as soon as warning complications occurred

Method of measurement

check list including possible adverse drug reactions following carbamazepine or pregabalin

Intervention groups

1

Description

Intervention group: Oral carbamazepine treatment group with a daily dose of 400 mg, for 8 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Oral Pregabalin treatment group with a daily dose of 400 mg, for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office of Dr Masoud Khoshbin - Pain fellow

Full name of responsible person

Dr Masoud Khoshbin

Street address

40th dead end, in front of Sepah, Shahid Sadoughi
Boulevard, Yazd- Iran

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masoudkhoshbin@iauyazd.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Ahmad Shajari

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

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Position

medical student

Latest degree

Medical doctor

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medical student

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available