

# 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

**City**

yazd

**Province**

Yazd

**Postal code**

8917694784

**Phone**

+98 35 3138 0155

**Email**

masoudkhoshbin@iauyazd.ac.ir

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

Islamic Azad University

**Full name of responsible person**

Dr Ahmad Shajari

**Street address**

Safaieh, Alam Square, Ali Ibn Abitaleb Medical School

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a\_shajari@yahoo.com

**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

**Street address**

Yazd - Shahid Sadoughi Boulevard, in front of Sepah,  
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masoudkhoshbin@iauyazd.ac.ir

**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**

Negar veysi

**Position**

medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

medical student

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Yazd, Safaieh, Mehravaran Aghigh Complex, Block 4

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**Email**

Negarveysi@yahoo.com

**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