

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

**A comparative study on the effects of oral N-acetylcystein and Pregabalin on the blood level of oxidative stress biomarkers in patients with painful diabetic neuropathy: a double-blind randomized clinical trial.**

### Protocol summary

#### Study aim

A Comparative study on the effects of oral NAC and Pregabalin on the level of oxidative Biomarkers and Nitrosation stress

#### Design

This study is a double-blind randomized clinical trial, phase 2, in which 140 eligible patients will be randomly assigned to the intervention pregabalin and NAC groups.

#### Settings and conduct

The eligible patients with painful diabetic neuropathy who will refer to Imam khomeini clinic and Shahid Beheshti hospital in Hamadan during the study period will be enrolled in the trial.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 70 years old; History of Diabetes mellitus type 2 at least one year ago; Hemoglobin A1C less than or equal to 9; diabetic neuropathy with NDS(Neuropathy Disability Score) greater than or equal to 6; VAS(Visual analogue scale) for pain at least 4 and NSS(Neuropathy symptom score) greater than or equal to 5; glomerular filtration rate more than. Exclusion criteria: type 1 DM; Pregnancy and breast feeding; Diabetic foot ulcer; having a neuropathy for reasons other than diabetes; History of cerebrovascular disease and discopathy; use other medications to relieve symptoms of neuropathy; use of alcoholic drinks or opioids.

#### Intervention groups

75 mg of pregabalin every 12 hours for 8 weeks compared with 600 mg of effervescent tablet of N-acetyl cysteine every 12 hour for 8 weeks.

#### Main outcome variables

VAS, serum level of lipid peroxidation, Nitric oxide, Total antioxidant capacity, thiol, activity of glutathione peroxidase, Catalase, superoxid dismutase.

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180814040795N2**

Registration date: **2019-01-21, 1397/11/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-21, 1397/11/01**

Update count: **0**

#### Registration date

2019-01-21, 1397/11/01

#### Registrant information

##### Name

Firozeh Sajedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1931

##### Email address

f.sajedi@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-08-22, 1397/05/31

#### Expected recruitment end date

2019-05-21, 1398/02/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

A comparative study on the effects of oral N-acetylcystein and Pregabalin on the blood level of oxidative stress biomarkers in patients with painful diabetic neuropathy: adouble\_blinde randomized clinical trial.

## Public title

A comparative study on the effects of oral N-acetylcystein and Pregabalin on the blood level of oxidative stress biomarkers in patients with painful diabetic neuropathy.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 30 to 70 years old History of type 2 Diabetes mellitus at least one year ago Hemoglobine A1C Less than or equal to 9 Diabetic neuropathy with NDS(Neuropathy Disablity Score) greater than or equal to 6, VAS(Visual analogue scale)fore pain at least 4 and NSS(Neuropathy symptom score) greater than or equal to 5 glomerular filtration rate more than 30 cc/min

### Exclusion criteria:

Type 1 diabetes pregnancy or breastfeeding Diabetic foot ulcer neuropathy for reasons other than diabetes History of cerebrovascular disease and discopathy Use other medications to relieve symptoms of neuropathy Use of alcoholic drink or opioids

## Age

From **30 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients will be unaware of the type of intervention; The physician who will examine the patients will not be aware of the intervention; Therefore, the trial will be run as double -blind.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamadan University of Medical sciences

##### Street address

Shahid Beheshti Hospital, Eram Blvd, Qa'em Square, Four research routes, Hamadan City.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517953371

#### Approval date

2018-06-08, 1397/03/18

#### Ethics committee reference number

IR.UMSHA.REC.1397.137

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic Polyneuropathy

#### ICD-10 code

E11.42

#### ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

## Primary outcomes

### 1

#### Description

Serum level of lipid peroxidation

#### Timepoint

Before intervention and 2 month after intervention

#### Method of measurement

kit

### 2

#### Description

serum level of Nitric oxide

#### Timepoint

Before intervention and 2 month after intervention

#### Method of measurement

kit

### 3

#### Description

serum level of total antioxidant capacity

#### Timepoint

Before intervention and 2 month after intervention

**Method of measurement**

kit

**4**

**Description**

Catalase activity

**Timepoint**

Before intervention and 2 month after intervention

**Method of measurement**

kit

**5**

**Description**

Activity of superoxide dismutase

**Timepoint**

Before intervention and 2 month after intervention

**Method of measurement**

kit

**6**

**Description**

serum level of thiol

**Timepoint**

Before intervention and 2 month after intervention

**Method of measurement**

kit

**7**

**Description**

Activity of Glutathione peroxidase

**Timepoint**

Before intervention and 2 month after intervention

**Method of measurement**

kit

**8**

**Description**

visual analogue scale

**Timepoint**

Before intervention, The end of the first month and The end of the second month

**Method of measurement**

Indicator

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: 600 mg of effervescent tablet of N-acetyi cysteine every12 hours for 8 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: 75mg Tablet pregabalin every 12 hours for 8 weeks.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hamadan Imam Khomeini Clinic

**Full name of responsible person**

Firoozeh Sajedi

**Street address**

Imam Khomeini clinic, Mirzadeh Eshqi St., Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838678

**Phone**

+98 81 3832 1371

**Email**

firozeh.sajedi@yahoo.com

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital in Hamadan

**Full name of responsible person**

Firoozeh Sajedi

**Street address**

Shahid Beheshti Hospital, Eram Blvd, Qa'em Square, Four research routes, Hamadan City

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**Email**

Firozeh.Sajedi@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Hamadan University of Medical Sciences, in front of

mardom park, shahid fahmideh Blvd., Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

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**Phone**

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**Email**

S\_Bashirian@yahoo.com

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

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Firoozeh Sajedi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Shahid Beheshti Hospital, Eram Blvd-Qa'em Square,  
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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Firoozeh Sajedi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Arman abdi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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Four research routes, Hamadan City

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**Postal code**

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**Email**

armanabdi393@gmail.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**

Undecided - It is not yet known if there will be 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