

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of oral N-acetylcysteine in comparing with pregabalin for pain management in patients with painful diabetic neuropathy.

Protocol summary

Study aim

Comparison of the effects of oral NAC and pregabalin on the control of pain in patients with neuropathy.

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 Hamedan 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 DM2 at least one year ago; HbA1C less than or equal to 9; diabetic neuropathy with NDS score greater than or equal to 6; VAS score for pain at least 4 and NSS score greater than or equal to 5; glomerular filtration rate more than. Exclusion criteria: type 1 DM; pregnancy or breast feeding; diabetic foot ulcer; having a neuropathy for reasons other than diabetes; history of cerebrovascular disease and discopathy; use of 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-acetylcysteine every 12 hours for 8 weeks.

Main outcome variables

VAS; serum level of lipid peroxidation; nitric oxide; total antioxidant capacity; thiol; activity of glutathione peroxidase; catalase; superoxide dismutase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180814040795N1**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

Registration date

2018-11-11, 1397/08/20

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

2018-08-21, 1397/05/30

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral N-acetylcysteine in comparing with pregabalin for pain

management in patients with painful diabetic neuropathy.

Public title

Evaluating the effects of oral N-acetylcysteine in comparing with pregabalin for pain management in patients with painful diabetic neuropathy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30 to 70 years old History of DM2 at least one year ago Hb A1C less than or equal to 9 Diabetic Neuropathy with NDS score greater than or equal to 6; VAS Score for pain at least 4 and NSS score greater than or equal to 5. Glomerular filtration rate more than 30cc/min

Exclusion criteria:

Type 1 diabetes Pregnancy or breast feeding Diabetic foot ulcer Neuropathy for reason 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

2

Groups that have been masked

- Participant
- Care provider

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 Hamedan University of Medical

sciences

Street address

Shahid Beheshti Hospital-Eram Blvd-Qa'em Square-Four research routes-Hamedan City

City

Hamedan

Province

Hamadan

Postal code

6517953371

Approval date

2018-06-18, 1397/03/28

Ethics committee reference number

IR.UMSHA.REC.1397.138

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

Visual analogue scale

Timepoint

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

Method of measurement

Indicator

2

Description

Sleep interference score

Timepoint

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

Method of measurement

Questionnaire

3

Description

Patient global impression of change

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Questionnaire

4

Description

Clinical global impression of change

Timepoint

Before intervention and 2 months after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 600mg of effervescent tablet of N-acetyi cysteine every 12 hours for 8 weeks .

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Imam Khomeini clinic

Full name of responsible person

Firozeh Sajedi

Street address

Imam Khomeini clinic ,Mirzadeh Eshqi St.,Hamedan

City

Hamedan

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 Hamedan

Full name of responsible person

Firoozeh Sajedi

Street address

Shahid Beheshti Hospital-Eram Blvd-Qa'em Square-
Four research routes-Hamedan City

City

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Phone

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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

سعید بشیریان Saeed Bashirian

Street address

Hamedan University of Medical Sciences, in front of
mardom park, shahid fahmideh Blvd., Hamedan

City

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Province

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6517838678

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

Firozeh Sajedi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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Email

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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

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Vida Faramarzi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

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