

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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: adouble_blinde 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 Nitrosatian 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 painfull 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 mor than. Exclusion criteria: type 1 DM; Pregnancy and breast feeding; Diabetic foot ulcer; having a neuropathy fore 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 every 12 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

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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

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6517838678

Phone

+98 81 3838 1010

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

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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

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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