Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of oral N-acetyl cysteine as an adjuvant therapy for pain management and serum level of oxidative stress bio-markers in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of of oral N-acetyl cysteine as an adjuvant therapy in combination with pregabalin in comparison with placebo on pain management and serum level of oxidative stress biomarkers in patients with painful diabetic neuropathy

Design

This study is a double-blind randomized clinical trial, phase II, in which 140 eligible patients will be randomly assigned to the intervention and control 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 type 2 diabetes at least one year ago; Hemoglobin A1c less than or equal to 10; diabetic neuropathy with NDS score greater than or equal to 6, NRS scores for pain at least 4 and NSS score greater than or equal to 5; glomerular filtration rate more than 30 Exit criteria: Type 1 diabetes; Pregnancy or breastfeeding; 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

Intervention group: 75 mg of pregabalin every 12 hours plus 600 mg of effervescent tablet of N-acetyl cysteine every 12 hours for 8 weeks. Control group: 75 mg of pregabalin every 12 hours plus oral placebo every 12 hours for 8 weeks.

Main outcome variables

NRS; sleep interference score; PGIC; CGIC; 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: **IRCT20150629022965N19**
Registration date: **2018-08-05, 1397/05/14**
Registration timing: **prospective**

Last update: **2019-08-15, 1398/05/24**
Update count: **1**

Registration date

2018-08-05, 1397/05/14

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy,Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral N-acetyl cysteine as an adjuvant therapy for pain management and serum level of oxidative stress bio-markers in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Public title

Evaluating the effects of oral N-acetyl cysteine as an adjuvant therapy for pain management and serum level of oxidative stress bio-markers in patients with painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 30 to 70 years old History of type 2 diabetes at least one year ago Hemoglobin A1c less than or equal to 10 Diabetic neuropathy with NDS score greater than or equal to 6, VAS scores for pain at least 4 and NSS score greater than or equal to 5 glomerular filtration rate more than 30

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 drinks or opioids

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

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

Pharmacy school, Hamadan University of Medical Sciences, in front of Mardom park, Shahid Fahmideh Blvd., Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.172

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 levels of nitric oxide

Timepoint

Before intervention and 2 month after intervention

Method of measurement

Kit

3

Description
Serum levels 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
Numeric rating scale
Timepoint
Before intervention, weekly until end of the study
Method of measurement
Questionnaire

9

Description
sleep interference score
Timepoint
Before intervention, weekly until end of the study
Method of measurement
Questionnaire

10

Description
Patient Global Impression of Change
Timepoint
Before intervention and 2 month after intervention
Method of measurement
Questionnaire

11

Description
Clinical Global Impression of Change
Timepoint
Before intervention and 2 month after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 75 mg of pregabalin every 12 hours plus 600 mg of effervescent tablet of N-acetyl cysteine every 12 hours for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: 75 mg of pregabalin every 12 hours plus oral placebo every 12 hours for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan Imam Khomeini clinic
Full name of responsible person
Firoozeh Sajedi
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Imam Khomeini clinic, Mirzadeh Eshqi St. , Hamedan
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2

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital of Hamadan

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

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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
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
Maryam Mehrpooya

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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
Not applicable
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