

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effects of topical gel Silymarin versus placebo as an adjuvant therapy on pain management in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of topical gel Silymarin versus placebo as an adjuvant therapy on pain management in patients with painful diabetic neuropathy

Design

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Beheshti Hospital in Hamadan city, involving 50 eligible patients with painful diabetic neuropathy. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years Diabetes mellitus type 1 or 2 Painful diabetic neuropathy Exclusion criteria: Pregnancy or breastfeeding Drug abuse Nondiabetic neuropathy Diabetic ulcer Liver or kidney disease

Intervention groups

Intervention group: Pregabalin 75 mg tablet at night plus 3% silymarin topical gel twice a day for 2 months Control group: Pregabalin 75 mg tablet at night plus placebo topical gel twice a day for 2 months

Main outcome variables

Primary outcome: Pain score, quality of life score, Secondary outcome: Local complication (redness, itching)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N501**

Registration date: **2024-02-29, 1402/12/10**

Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**

Update count: **0**

Registration date

2024-02-29, 1402/12/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-25, 1403/01/06

Expected recruitment end date

2024-08-15, 1403/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of topical gel Silymarin versus placebo as an adjuvant therapy on pain management in patients with

painful diabetic neuropathy: a double-blind randomized clinical trial

Public title

Effects of topical gel Silymarin versus placebo as an adjuvant therapy on pain management in patients with painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years Diabetes mellitus type 1 or 2 Painful diabetic neuropathy

Exclusion criteria:

Pregnancy or breastfeeding Drug abuse Nondiabetic neuropathy Diabetic ulcer Liver or kidney disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. The analyzer responsible for evaluating the trial's results will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a double-blind study.

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

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

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Province

Hamadan

Postal code

6517838695

Approval date

2024-02-24, 1402/12/05

Ethics committee reference number

IR.UMSHA.REC.1402.727

Health conditions studied

1

Description of health condition studied

Painful diabetic neuropathy

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Pain score

Timepoint

Before intervention and one and two months later

Method of measurement

Using visual analog scale (VAS)

2

Description

Quality of life score

Timepoint

Before the intervention and one and two months later

Method of measurement

Using the World Health Organization Quality of Life Questionnaire

Secondary outcomes

1

Description

Local complication (redness, itching)

Timepoint

One and two months later the intervention

Method of measurement

By taking history and clinical examination

Intervention groups

1

Description

Intervention group: Pregabalin 75 mg tablet at night plus 3% silymarin topical gel twice a day for 2 months

Category

Treatment - Drugs

2

Description

Control group: Pregabalin 75 mg tablet at night plus placebo topical gel twice a day for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital in Hamadan city

Full name of responsible person

Mohammad Reza Khodarahmi Ghahnavieh

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Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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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

Mohammad Reza Khodarahmi Ghahnavieh

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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