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

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Name of organization / entity
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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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1

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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
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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