

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of topical Citrullus colocynthis fruit oil efficacy in the pain, electrodiagnostic findings and quality of life of patients with painful peripheral diabetic neuropathy

Protocol summary

Summary

aim of study: Evaluation of topical Citrullus colocynthis fruit oil efficacy in treatment of painful peripheral diabetic neuropathy Study design: Randomized double blind placebo-controlled clinical trial Study population: Patients with painful diabetic neuropathy attending SUMS endocrinology clinic Inclusion criteria: Patients with diabetes mellitus with painful neuropathy Exclusion criteria: Another painful condition that was difficult to distinguish from painful diabetic peripheral neuropathy Sample size: 60 patients (two groups) Interventions: Topical Citrullus colocynthis fruit oil/ vehicle oil Time period: 12 week Outcome measures: Neuropathic Pain Scale (NPS) score WHOQOL-BREF questionnaire score Nerve Conduction velocity values

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108117297N1**
Registration date: **2015-01-19, 1393/10/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-19, 1393/10/29

Registrant information

Name

Mojtaba Heydari

Name of organization / entity

Shiraz university of medical science

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical Citrullus colocynthis fruit oil efficacy in the pain, electrodiagnostic findings and quality of life of patients with painful peripheral diabetic neuropathy

Public title

Topical Citrullus colocynthis fruit oil in painful peripheral diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Controlled type 1 or 2 diabetes mellitus; Painful Peripheral diabetic neuropathy for more than 3 months; Age more than 18 years old; Patients consent on enrolling study and admitting study protocol Exclusion criteria: Other causes of pain in lower extremities like lumbar disk herniation; Ulcerative lesions in lower extremities; Dermatitis; Pregnancy; Lactation; Citrullus colocynthis allergy; Unstable cardiac, neurological or renal disease; Diagnosed other types of

neuropathy.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization type: Block randomization Blinding with use of vehicle oil as placebo

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Vice chancellor for research, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran.

City

Shiraz

Postal code**Approval date**

2014-04-14, 1393/01/25

Ethics committee reference number

CT-9377-7007

Health conditions studied**1****Description of health condition studied**

Painful diabetic polyneuropathy

ICD-10 code

G63.2

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes**1****Description**

Neuropathic Pain Scale (NPS) score

Timepoint

Before the study and 12 weeks after the intervention

Method of measurement

Visual Scale

Secondary outcomes**1****Description**

Nerve Conduction velocity

Timepoint

Before the study and 12 weeks after the intervention

Method of measurement

m/s by NCV

2**Description**

WHOQOL-BREF score

Timepoint

Before the study and 12 weeks after the intervention

Method of measurement

Questionnaire (standard)

Intervention groups**1****Description**

Citrullus colocynthis fruit oil: 1cc three times per day, application on the plantar and dorsal foot surface , without massage

Category

Treatment - Drugs

2**Description**

Vehicle oil (Sesame oil): 1cc three times per day, application on the plantar and dorsal foot surface , without massage

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz University of Medical Sciences

Full name of responsible person

Mojtaba Heydari

Street address**City**

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maohammad Hosein Dabaghmanesh

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

PhD candidate

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty