Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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

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Sponsors / Funding sources

1

Sponsor
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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

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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