

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1235 7679

##### Email address

mheydari@sums.ac.ir

##### 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

**Street address**

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

**City**

Shiraz

**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**

Mojtaba Heydari

**Position**

PhD candidate

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mesbah Shams

**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**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*