Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of effect of Citrullus colocynthis oil with placebo on pain in patients with painful diabetic neuropathy

Protocol summary

Summary

Hanzal or Bitter apple (Citrullus colocynthis) is used in Iranian traditional medicine to relieve pain. Recent researches have also shown its analgesic effect in animal studies. The objective of this study is to assess the effects of Hanzal oil on pain in painful diabetic neuropathy. In this study, 60 patients with painful diabetic neuropathy in the lower extremities who their severity of pain with visual analogue scale are more than 30 mm, and are taking routine treatments are included in the study after ruling out the other causes of neuropathy. Then they are randomly divided into two groups of 30 cases. One group receives local Hanzal oil 5 puffs twice a day (at least two hours after taking glucose-lowering drugs), and the other group receives placebo in the same way. Oral medications continue and topical pain killers discontinue. One and two months later, severity of pain will be assessed with visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211151957N4**
Registration date: **2012-12-27, 1391/10/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-27, 1391/10/07

Registrant information

Name

Fataneh Hashem Dabaghian

Name of organization / entity

Research Institute for Islamic and Complementary Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 3395 0152

Email address

fatanehdabaghian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Research Institute for Islamic and Complementary Medicine (Tehran University of Medical sciences)

Expected recruitment start date

2012-12-21, 1391/10/01

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

Comparison of effect of Citrullus colocynthis oil with placebo on pain in patients with painful diabetic neuropathy

Public title

Effect of Hanzal oil on pain of diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-80 years, type 2 diabetes mellitus, painful diabetic neuropathy, pain in lower limbs, rule out other causes of neuropathy, neuropathy for more than 6 months, severity of pain more than 3 mm in visual scale of pain, written informed consent, Exclusion criteria: glycosylated hemoglobin more than 10, taking insulin, sever acute pain that requires lidocaine, active or

infected wounds in lower limbs, amputation of lower limbs, pregnancy, lactation

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization will be conducted by the table of random numbers. Color of oils and shape of containers of drug and placebo are similar. Blinding will be performed in patients, physician, and data analyzer.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Institute for Islamic and Complementary Medicine (Tehran University of Medical sciences)

Street address
No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City
Tehran

Postal code

Approval date
2012-03-06, 1390/12/16

Ethics committee reference number
ط م/ 26 پ/1699

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy

ICD-10 code
G 63.2*

ICD-10 code description
Diabetic Polyneuropathy

Primary outcomes

1

Description
pain

Timepoint
before intervention, 1 month and 2 months after intervention

Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Group 1: Topical Hanzal oil 5 puffs twice daily on pain area. Hanzal oil has been made by traditional pharmacist in the Research Institute for Islamic and Complementary Medicine. To prepare hanzal oil, aquous extract of hanzal fruits was mixed and heated with twice its volume of sesame oil until the water evaporates and oil remains. Oil for 1 month consumption of each patient is placed in spray containers.

Category
Treatment - Drugs

2

Description
Topical paraffin oil 5 puffs twice daily on pain area. It is placed in spray containers for 1 month consumption of each patient.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Research Center of Yazd

Full name of responsible person
Mohammad Afkhami

Street address
No. 12, Jomhuri eslami Blvd., Yazd, IRAN

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for Islamic and Complementary

Medicine (Tehran University of Medical sciences)

Full name of responsible person

seied Ashrafeddin Goushegir

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Institute for Islamic and Complementary Medicine (Tehran 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

Research Institute for Islamic and Complementary Medicine (Tehran University of Medical sciences)

Full name of responsible person

Fataneh Hashem Dabaghian

Position

Assistant professor

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City

Tehran

Postal code

Phone

+98 21 3395 0152

Fax

Email

fataneh.dabaghian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Institute for Islamic and Complementary Medicine (Tehran University of Medical sciences)

Full name of responsible person

Fataneh Hashem Dabaghian

Position

Assistant professor

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City

Tehran

Postal code

Phone

+98 21 3395 0152

Fax

Email

fataneh.dabaghian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research Institute for Islamic and Complementary Medicine (Tehran University of Medical sciences)

Full name of responsible person

Fataneh Hashem Dabaghian

Position

Assistant professor

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City

Tehran

Postal code

Phone

+98 21 3395 0152

Fax

Email

fataneh.dabaghian@yahoo.com

Web page address

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