

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluate the effect of Peganum Harmala on glycemic index in diabetic patient, a triple-blind randomized, placebo controlled trial

Protocol summary

Study aim

This study aimed to the Effect of Peganum Harmala patients with type 2 diabetic deals.

Design

A randomised controlled clinical trial and triple blind ,parallel study

Settings and conduct

This study is conducted at Shahid Beheshti Hospital in Qom and is blinded by placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: type 2 diabetes over a year; age group 40-75; Distal polyneuropathy resolutions based on questionnaires Michigan; HbA1C 8% -10% Exclusion criteria: Kidney, liver, and heart failure based on the tests, history and physical exam; High blood pressure more than 180 mm Hg and advanced diabetic Retinopathy; The recent use of drugs for neuropathy {gabapentin , nortriptyline}; Fever; Pregnancy and lactation; History of amputation

Intervention groups

patient with type 2 diabetes which is divided into two groups of Peganum Harmala capsule and placebo capsule .placebo similar to the drug.

Main outcome variables

Fasting blood sugar

General information

Reason for update

Acronym

QDS

IRCT registration information

IRCT registration number: **IRCT20170112031893N3**

Registration date: **2018-11-25, 1397/09/04**

Registration timing: **prospective**

Last update: **2018-11-25, 1397/09/04**

Update count: **0**

Registration date

2018-11-25, 1397/09/04

Registrant information

Name

Hossein Yusefi

Name of organization / entity

Qom University of medical science

Country

Iran (Islamic Republic of)

Phone

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Email address

driran1399@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effect of Peganum Harmala on glycemic index in diabetic patient, a triple-blind randomized, placebo controlled trial

Public title

Evaluate the effect of Peganum Harmala on glycemic index in diabetic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

type 2 diabetes over three year age group 40-75 Distal polyneuropathy resolutions based on questionnaires Michigan HBA1C8% -10%

Exclusion criteria:

Kidney, liver, and heart failure based on the tests, history and physical exam High blood pressure more than 180 mm Hg and advanced ; diabetic Retinopathy Pregnancy and lactation History of amputation Fever the recent use of drugs for neuropathy {gabapentin , nortriptyline} Consumers of medicines that induce delayed gastric emptying such as: Acarbose, Miglitol, Exenatid, benzodiazepines, calcium channel blockers, narcotics, alpha-2 adrenergic receptor agonists such as clonidine, tricyclic antidepressants, dopamine agonists, cholinergic muscarinic receptor antagonists, Octreotide, phenothiazines, cyclosporine

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated into two groups using random numbers table developed by Random Allocation Software

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical

Street address

Vice chancellor for research of Qom University of Medical Sciences, Safashar road, Qom, Iran

City

QOM

Province

Ghoush

Postal code

87366-37169

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.MUQ.REC.1397.132

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

fasting blood sugar

Timepoint

pre and early post-treatment

Method of measurement

Based on Laboratory

Secondary outcomes

1

Description

Distal polyneuropathy

Timepoint

Before and 3 months after the intervention

Method of measurement

Michigan Questionnaire A

Intervention groups

1

Description

Intervention group: The group used Peganum Harmala capsules amount 1 gram for 3 months, every day

Category

Treatment - Drugs

2

Description

Control group: The group used placebo capsules amount 1 gram for 3 months, every day

Category

Placebo

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

Shahid Behashti Hospital

Full name of responsible person

Mahmud Perham

Street address

Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Hossein Saghafi

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Number 83, Alley 4, Alley 1.1, Safashahr Street

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Qom 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****Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Muhammad hossein Yusefi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Diabetes

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Latest degree

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

With attention due to the type of study and publication of
the article, there was no need to mention this

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available