Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 group40-75;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;The recent use of drugs for neuropathy {gabapentin , nortriptyline};Fever;Pergnancy 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
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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 group40-75 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 Pergnancy 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

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Province

Ghoum

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 Labratory

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
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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
Ghoum University of Medical Sciences
Full name of responsible person
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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
Ghoum University of Medical Sciences
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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