

# 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

+98 25 3886 0146

###### 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

**City**

Qom

**Province**

Ghous

**Postal code**

3719964797

**Phone**

+98 25 3886 0146

**Email**

Mahmoud51dr@yahoo.com

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

Ghous University of Medical Sciences

**Full name of responsible person**

Hossein Saghafi

**Street address**

Number 83, Alley 4, Alley 1.1, Safashahr Street

**City**

Qom

**Province**

Ghous

**Postal code**

3719964797

**Phone**

+98 25 3886 0146

**Email**

driran1399@gmail.com

**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

**Street address**

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

**City**

Qom

**Province**

Ghous

**Postal code**

3719964797

**Phone**

+98 25 3886 0146

**Email**

huqom1394@yahoo.com

**Person responsible for scientific 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

**Street address**

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

**City**

Qom

**Province**

Ghous

**Postal code**

3713649373

**Phone**

+98 25 3886 0146

**Email**

driran1390@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Muhammad hossein Yusefi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Diabetes

**Street address**

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

**City**

Qom

**Province**

Ghoum

**Postal code**

3719964797

**Phone**

+98 25 3886 0146

**Email**

driran1390@yahoo.com

## 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