Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The combination effect of five herbal drugs" Peganum harmala,Quercus infectoria,Vaccinium myrtillus, Citrullos colocynthis, Securigera securidaca" on blood glucose in adults with type 2 diabetes mellitus

Protocol summary

Summary

This cross over double blind clinical trial was designed to evaluate the combination effect of five plants " Peganum harmala,Quercus infectoria, Vaccinium myrtillus, Citrullus colocynthis , Securigera securidaca" on blood sugar in adults with type 2 diabetes referred to Imam Khomeini hospital, diabetes center in Sari. The study population consist of 20 patients that will be divided into two groups randomly. One Group will receive 500 mg of prepared powder of drug (fruit of Quercus infectoria , seed of Securigera securidaca , fruit of Vaccinium myrtillus whichever 125mg and fruit of Citrullus colocynthis and seed of Peganum harmala whichever 62.5mg)and other group will receive placebo for 8 weeks. After one week washout the drug and placebo will be replaced for next 8 weeks. Blood pressure, Fasting blood sugar (FBS), serum insulin and HbA1C will be measured at baseline of each period . After 1, 2, 4 and 8 weeks, the patients will be examined by a general physician who is blind to type of treatment. The number of remained drug will be counted and the adverse effects of drug will be recorded. Measurement of FBS will be repeated after 4 and 8 weeks and serum insulin, HbA1C after 8 weeks in each period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811143180N1**
Registration date: **2010-06-06, 1389/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-06, 1389/03/16

Registrant information

Name
Zahra Kashi
Name of organization / entity
Mazandaran university of medical sciences
Country
Iran (Islamic Republic of)
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+98 15 1226 1701
Email address
zkashi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2009-08-01, 1388/05/10

Expected recruitment end date

2010-10-19, 1389/07/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combination effect of five herbal drugs" Peganum harmala,Quercus infectoria,Vaccinium myrtillus, Citrullos colocynthis, Securigera securidaca" on blood glucose in adults with type 2 diabetes mellitus

Public title

The combination effect of five herbal drugs" Peganum harmala, Quercus infectoria,Vaccinium myrtillus, Citrullos colocynthis, Securigera securidaca" on blood glucose in adults with type 2 diabetes mellitus

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 30 to 80, HbA1C 6.5 to 8% .Exclusions criteria: Immune deficiency, pregnancy and lactation, cardiovascular disease, currently receiving corticosteroids and thiazide, uncontrolled thyroid dysfunction, acute infection ,history of diabetic ketoacidosis , Cr>1.5 for male, Cr>1.2 for female, acute hepatitis, cirrhosis, proliferative retinopathy and severe weight loss (at least 10% during last 6 months)
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Mazandaran University of medical sciences
Street address
Imam Sq., Valiye asr highway
City
Sari
Postal code
Approval date
2010-01-06, 1388/10/16
Ethics committee reference number
94-87

Health conditions studied

1

Description of health condition studied
diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1C
Timepoint
before and 8 weeks after intervention
Method of measurement
laboratory

2

Description
FBS
Timepoint
before and 4 and 8 weeks after intervention
Method of measurement
laboratory

Secondary outcomes

1

Description
serum insulin
Timepoint
before and 8 weeks after intervention
Method of measurement
laboratory

2

Description
lipid profile
Timepoint
before and 4 and 8 weeks after intervention
Method of measurement
laboratory

3

Description
weight
Timepoint
before and 8 weeks after intervention
Method of measurement
weight Scale

Intervention groups

1

Description
Intervention group: capsule contains 500 mg of combination of 5 herbal drug, twice daily for 8 weeks
Category

Treatment - Drugs

2

Description
Placebo group: flour of bean capsul, twice daily for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes center of Imam Khomeini hospital
Full name of responsible person
Parisa Rabie
Street address
Imam Khomeini hospital, Razi Street
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences and Health
Full name of responsible person
Dr Ahmad Ali Enayati
Street address
Deputy of research and technology, Mazandaran university of medical sciences
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences and Health
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
Mazandaran University of Medical Sciences and Health
Full name of responsible person
Zahra Kashi
Position
endocrinologist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaranl Univercity of medical sciences and Health services
Full name of responsible person
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Person responsible for updating data

Contact
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Fax
Email

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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