Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Investigating Antihyperglycemic and Antihyperlipidemic Effects of Dorema aucheri Plant Powder in Type II Diabetic Patients

Protocol summary

Summary

The aim of present study was to investigate the effects of Dorema aucheri on hyperglycemia and hyperlipidemia conditions in type II diabetic patients. A minimum of 2-year experience with type II diabetes diagnosed by a physician endocrinologist and 40-65 years of age was regarded as inclusion criteria and no lactation/pregnancy, not receiving insulin therapy; not using medications or supplementation known to alter sugar/lipid metabolism; or clinical history of acute disease was regarded as exclusion criteria. 150 diabetic patients would be randomly divided into three groups: 1) receiving placebo, 2) 100 mg or 2) 500 mg plant powder, daily before lunch for 45 days. The blood levels of sugar and lipids would be measured before the experiment and after 45 days at the end of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123120502N1**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

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Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Diabetes Research Center, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-10, 1391/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating Antihyperglycemic and Antihyperlipidemic Effects of Dorema aucheri Plant Powder in Type II Diabetic Patients

Public title

Anti-diabetic effects of Dorema aucheri

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a minimum of 2-year experience with type II diabetes diagnosed by a physician endocrinologist; 40-65 years of age, Exclusion criteria: free of dietary restrictions/food allergies; not receiving insulin therapy; not using medications or supplementation known to alter sugar/lipid metabolism; no clinical history of cardiovascular, hepatic, gastrointestinal, or renal disease; no recent history of smoking.

Age

No age limit

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The medical ethics committee at Shahid Sadouqhi University of Medical Sciences
Street address
The ethics committee office at Vice chancellor of research, Shahid Sadouqhi University of Medical Sciences, Yazd, Iran
City
Yazd
Postal code
Approval date
2013-02-18, 1391/11/30
Ethics committee reference number
168931

Health conditions studied

1

Description of health condition studied
Patients with Type II Diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Blood levels of glucose
Timepoint
At the baseline of experiment and after 45 days at the end of experiment
Method of measurement
Blood testing

Secondary outcomes

1

Description
The blood level of cholesterol
Timepoint
At the baseline of experiment and after 45 days at the end of experiment
Method of measurement
Blood testing

Intervention groups

1

Description
Placebo group 3): receiving placebo capsules, daily before lunch + anti-diabetic medication, for 45 days
Category
Placebo

2

Description
Intervention group 2): receiving 500 mg capsules containing Dorema aucheri (DA) powder, daily before lunch + anti-diabetic medication, for 45 days
Category
Treatment - Drugs

3

Description
Intervention group 1): receiving 100 mg capsules containing Dorema aucheri (DA) powder, daily before lunch + anti-diabetic medication, for 45 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd diabetes research center, Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Fatemeh Pourrajab
Street address
Yazd diabetes research center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr Amirhoushang Mehrparvar
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Vice Chancellor of research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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

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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