Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Tribulus terrestris hydroalcoholic extract on blood glucose and lipids profile in 40 to 60 years old women with Diabetes Type II

Protocol summary

Summary

The objective of this study is to investigate the effects of Tribulus terrestris (TT) extract on blood glucose and lipid parameters in patients with type 2 diabetes mellitus.The study was carried out as a randomized double-blind, placebo controlled trial. Major inclusion criteria were not to use herbal remedies at least for a month before the study; not to be treated with hormonal compounds; to be controlled with oral hypoglycemic drugs; not to have any other chronic disease such as renal, hepatic or cardiovascular diseases, not to use vasodilators; negative family history of breast cancer; no diagnosed complication of diabetes or uncontrolled hypertension. Through the study,100 diabetic women will be divided into two equal groups (drug and placebo). Blood samples for blood sugar and lipid levels will be get before and after the intervention. The relevant information will be collected and statistical analysis will be conducted. The intervention group will receive 1 gram of TT extract divided in two doses for three consecutive months. In the control group, placebo will be given in similar amount and duration. Main outcome measures will be fasting blood glucose, 2 hours postprandial glucose, glycated hemoglobin, triglycerides, total cholesterol, low density lipoprotein and high density lipoprotein

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922971N1**
Registration date: **2015-12-02, 1394/09/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Nasrin Babadaei Samani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-20, 1393/09/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tribulus terrestris hydroalcoholic extract on blood glucose and lipids profile in 40 to 60 years old women with Diabetes Type II

Public title

Effect of Tribulus terrestris extract on blood glucose and lipids profile

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Willingness to cooperate and participate in the study; give written informed consent

by the patient; not to use herbal remedies at least for a month before the study; not to be treated with hormonal compounds; to be controlled with oral hypoglycemic drugs; not to have any other chronic disease such as renal, hepatic or cardiovascular diseases, not to use vasodilators; negative family history of breast cancer; no diagnosed complication of diabetes or uncontrolled hypertension. Exclusion criteria: insulin therapy; non-compliance to the study protocol; Any sensitivity to TT or unusual drug side effects.

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
randomization using permutation block

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Central building of Shiraz University of Medical Sciences, Zand street, Shiraz

City
Shiraz

Postal code
71345-1978

Approval date
2014-11-05, 1393/08/14

Ethics committee reference number
9378-7208

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1c

Timepoint
Before the intervention, three months after intervention

Method of measurement
According mg/dl using lab kit

2

Description
FBS

Timepoint
Before the intervention, three months after intervention

Method of measurement
According mg/dl using lab kit

3

Description
TG

Timepoint
Before the intervention, three months after intervention

Method of measurement
According mg/dl using lab kit

4

Description
Cholesterol

Timepoint
Before the intervention, three months after intervention

Method of measurement
According mg/dl using lab kit

5

Description
HDL

Timepoint
Before the intervention, three months after intervention

Method of measurement
According mg/dl using lab kit

6

Description
LDL

Timepoint
Before the intervention, three months after intervention

Method of measurement

According mg/dl using lab kit

7

Description
2hpp
Timepoint
Before the intervention, three months after intervention
Method of measurement
According mg/dl using lab kit

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Tribulus Terrestris, capsules 500 mg twice daily for three months.
Category
Treatment - Drugs

2

Description
control group: Cellulose, 500 mg, twice daily for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Shahid Motahari clinic
Full name of responsible person
Nasrin Babadaei Samani
Street address
next to Namazi Hospital, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Central Building of University of Medical Sciences, Zand Ave, Shiraz.
City
Shiraz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shiraz 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

Contact
Name of organization / entity
Shiraz Medical Science University
Full name of responsible person
Nasrin Babadaei Samani
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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