

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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)

##### Phone

+98 31 1111 1111

##### Email address

babadaei@sums.ac.ir

#### 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

**Position**

Master of Science

**Other areas of specialty/work**

**Street address**

Central Building of University of Medical Sciences, Zand street, Shiraz

**City**

Shiraz

**Postal code**

00

**Phone**

00

**Fax**

**Email**

samani\_nasrin@yahoo.com; babadaei@sums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz Medical Science University

**Full name of responsible person**

Azam Jokar

**Position**

master of science

**Other areas of specialty/work**

**Street address**

Central Building of University of Medical Sciences, Zand Ave, Shiraz

**City**

Shiraz

**Postal code**

00

**Phone**

00

**Fax****Email**

jokara@sums.ac.ir; babadaei@sums.ac.ir;

samani\_nasrin@yahoo.com

**Web page address**

00

**Phone**

00

**Fax****Email**

samani\_nasrin@yahoo.com; babadaei@sums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz Medical science University

**Full name of responsible person**

Nasrin Babadaei Samani

**Position**

Master of Science

**Other areas of specialty/work****Street address**Central Building of University of Medical Sciences,  
Zand Ave, Shiraz**City**

Shiraz

**Postal code****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*