

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Diabetes Explanation & Evaluation the Effect of Ziabitos capsule consumption on Blood Glucose Control, in Patients with Type 2 Diabetes, in Traditional Iranian medicine.

Protocol summary

Summary

The study is a clinical trial of patients (Before & After Study). the aim of clarifying the effect of Ziabitos capsule consumption on Blood Glucose Control, in Patients with Type 2 Diabetes. In this study, 40 patients referred to the endocrine clinic and laboratories in martyr Mostafa Khomeini hospital and shahed traditional medicine clinic With uncontrolled diabetes (HbA1c > 7%) and treated with oral diabetes medications (one or more Pharmaceutical group) are being studied. study period in this study is Four-week. Ziabitos capsule consumption is three times daily, immediately before the meal and the dose of each capsules is 500 mg (1500 mg in day). At the beginning and end of study for all patients; Cr, BUN, Na, K, SGPT, SGOT, TG, CHOL, FRUCTOSAMINE, BS (2hpp), FBS, CBC, serum Alb, HbA1c (in beginning of study) and GFR levels are measured. before and after quantitative variables are compared with paired Student's t test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108107286N1**
Registration date: **2011-11-06, 1390/08/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-11-06, 1390/08/15

Registrant information

Name

Majid Asghari

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5527 7400

Email address

asghari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed university

Expected recruitment start date

2011-10-12, 1390/07/20

Expected recruitment end date

2011-12-06, 1390/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Diabetes Explanation & Evaluation the Effect of Ziabitos capsule consumption on Blood Glucose Control, in Patients with Type 2 Diabetes, in Traditional Iranian medicine.

Public title

Ziabitos capsule effect on blood glucose control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age: 30 - 70 years 2- Uncontrolled Type 2 Diabetes: (HbA1c >7%) 3- Treated with oral diabetes medications (one or more Pharmaceutical group) 4- Over at least a month, since the addition of anti-diabetic drug dosage or prescribe a new anti-

diabetic drug Exclusion criteria: 1- GFR (Glomerular Filtration Rate) < 60 ml/mi 2- Serum Alb < 4 gr/dl 3 - High SGOT and SGPT: more than three times the normal

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University

Street address

Shahed university, Opposite the Shrine of Imam Khomeini, Freeway at Tehran - Qom, Tehran.

City

Tehran

Postal code

3319118751

Approval date

2011-05-31, 1390/03/10

Ethics committee reference number

4/112251

Health conditions studied

1

Description of health condition studied

Diabet

ICD-10 code

E10-E14

ICD-10 code description

Diabetes Mellitus

Primary outcomes

1

Description

2h postparandial blood suger

Timepoint

Before and four weeks after Intervention

Method of measurement

Mg per deciliter and a lab kit

2

Description

Serum Fructosamine

Timepoint

Before and four weeks after Intervention

Method of measurement

Micromol per liter and a lab kit

3

Description

Fasting Blood Sugar

Timepoint

Before and four weeks after Intervention

Method of measurement

Mg per deciliter and a lab kit

Secondary outcomes

1

Description

Triglycerid

Timepoint

Before and four weeks after Intervention

Method of measurement

Mg per deciliter and a lab kit

2

Description

Total cholestrol

Timepoint

Before and four weeks after Intervention

Method of measurement

Mg per deciliter and a lab kit

3

Description

Aspartat Aminotransferase

Timepoint

Before and four weeks after Intervention

Method of measurement

unit per liter and a lab kit

4

Description

Blood Urea Nitrogen

Timepoint

Before and four weeks after Intervention
Method of measurement
Meq per liter and a lab kit

5

Description
Cratinin
Timepoint
Before and four weeks after Intervention
Method of measurement
Meq per liter and a lab kit

6

Description
Alanin Aminotransferase
Timepoint
Before and four weeks after Intervention
Method of measurement
unit per liter and a lab kit

7

Description
Sodium (Na)
Timepoint
Before and four weeks after Intervention
Method of measurement
Meq per liter and a lab kit

8

Description
Potasium(K)
Timepoint
Before and four weeks after Intervention
Method of measurement
Meq per liter and a lab kit

9

Description
Serum Albumin
Timepoint
Before and four weeks after Intervention
Method of measurement
gr per deciliter and a lab kit

10

Description
Glumerolar Filtration Rate (GFR)
Timepoint
Before and four weeks after Intervention
Method of measurement
MI Per Min And Glomerular filtration rate calculated using the formula

11

Description
Complit Blood Count (CBC)
Timepoint

Before and four weeks after Intervention
Method of measurement
Based on the number And Lab kit

12

Description
Hemoglobin A1c Glycosilate (HbA1c)
Timepoint
Before of Intervention(in beginning of study)
Method of measurement
per cent and a lab kit

Intervention groups

1

Description
Ziabitos, 500 mg oral capsule, three times daily, for four weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Martyr Mostafa Khomeini Hospital and Shahed Traditional medicine clinic
Full name of responsible person
Majid Asghari
Street address
Martyr Mostafa Khomeini Hospital And Salamat clinic, the streets of Italy, Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University Research
Full name of responsible person
Mohsen Naseri
Street address
Salamat clinic, next to martyr Mostafa Khomeini hospital, Italy street, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University Research
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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Majid Asghari

Position

Assistant Phd doctorate in traditional medicine in Iran

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Position

PhD Candidate in Traditional Medicine in Iran

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shahed university

Full name of responsible person

Majid Asghari

Position

Phd Condidate in Traditional Medicine in Iran

Other areas of specialty/work**Street address**

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City

Tehran

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