Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Studen'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)

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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 Filteration Rate (GFR)

Timepoint

Before and four weeks after Intervention

Method of measurement

Ml 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

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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Person responsible for scientific 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