Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of " conventional medicine,blood sugar"(combination of powder of Urtica dioica leaf %20,powder of Morus nigra leaf %10,powder of Allium Sativum %20 ,powder of Trigonella foenum-graceum or Fenugreek seed%20 ,powder of Junglans Regia leaf %20 ,powder of Cinnamomum Zeylanicum %10)on the Insulin resistance of patients with Diabetes Mellitus type II

Protocol summary

Summary

Considering the increasing prevalence of diabetes in Iran and tendency of patients toward using herbal medicines instead of conventional (chemical) pharmaceuticals, the current study aimed at evaluating the effect of herbal medicine of Diabites (including nettle leaf, blackberry leaf, garlic powder, fenugreek powder, walnut leaf, and cinnamon powder) on the level of blood sugar in patients with diabetes. According to the results of the study, the intervention mainly affected fasting blood sugar (FBS), 2 hours post-prandial blood sugar (2hppBS), and hemoglobin A1c (HBA1c), followed by systolic and diastolic blood pressures, homeostasis model assessment-estimated insulin resistance (HOMA-IR), urea, creatinine, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), C-reactive protein (CRP), triglyceride (TG), cholesterol (CHOL), high-density lipoprotein (HDL), and low-density lipoprotein (LDL) as the secondary effects. The current double-blind, placebo-controlled, randomized clinical trial, a single-center study, was conducted on 76 patients with diabetes, in the age range of 25 to 70 years. The study cases included the patients with diabetes referred to the Oncology Clinic at Shahid Beheshti Hospital in Qom, Iran. The patients were the candidates for insulin injection, but had no willingness to inject. At the beginning of the study, the cases were assigned to 2 groups of experiment and placebo, by the random block sampling method. The experiment group received Diabites 3 times a day, each time 1 capsule, in addition to the previously prescribed medicines, and the placebo group received the placebo by the same program in addition to the previously prescribed medicines for 12 weeks. The inclusion criteria were: the age range of 25 to 70 years for both genders, FBS >130 mg/dL and 2hppBS >180 mg/dL; having cardiovascular, renal, and/or liver diseases were also considered as the exclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011826097N1**
Registration date: **2017-05-02, 1396/02/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-02, 1396/02/12

Registrant information

Name
Jamshid Vafaeemanesh
Name of organization / entity
Qom University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 252931933
Email address
j.vafaeemanesh@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date
2014-03-20, 1392/12/29
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
The effect of " conventional medicine,blood sugar"(combination of powder of Urtica dioica leaf %20,powder of Morus nigra leaf %10,powder of Allium Sativum %20 ,powder of Trigonella foenum-graceum or Fenugreek seed%20 ,powder of Junglans Regia leaf %20 ,powder of Cinnamomum Zeylanicum %10)on the Insulin resistance of patients with Diabetes Mellitus type II

Public title
The effect of " conventional medicine,blood sugaron the Insulin resistance of patients with Diabetes Mellitus type II
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:the age range of 25 to 70 years for both genders, FBS >130 mg/dL and 2hppBS >180 mg/dL, uncontrolled BS with two decreased BS oral drug in patient the candidates for insulin injection, but had no willingness to inject. Exclusion criteria: cardiovascular,kidney and liver disease; pregnancy; breast feeding
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qom University of Medical Sciences
Street address
Qom University of Medical Sciences Pardis، Qom
City
Qom
Postal code
3713649373
Approval date
2016-06-22, 1395/04/02
Ethics committee reference number
Ir.muq.rec.1395.42

Health conditions studied

1

Description of health condition studied
diabet mellitus type2
ICD-10 code
E11
ICD-10 code description
non-Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
FBS
Timepoint
Before intervention, after 6 weeks, after intervention(after 12 weeks)
Method of measurement
blood test (Mg per deciliter)

2

Description
HbA1c
Timepoint
Before intervention, after 6 weeks, after intervention(after 12 weeks)
Method of measurement
blood test (Mg per deciliter)

3

Description
HOMA-IR
Timepoint

Before intervention, after 6 weeks, after intervention(after 12 weeks)

Method of measurement

blood test (Mg per deciliter)

Secondary outcomes

1

Description

TG

Timepoint

Before intervention, after 6 weeks, after intervention(after 12 weeks)

Method of measurement

blood test (Mg per deciliter)

2

Description

CHOL

Timepoint

Before intervention, after 6 weeks, after intervention(after 12 weeks)

Method of measurement

blood test (Mg per deciliter)

3

Description

LDL

Timepoint

Before intervention, after 6 weeks, after intervention(after 12 weeks)

Method of measurement

blood test (Mg per deciliter)

4

Description

HDL

Timepoint

Before intervention, after 6 weeks, after intervention(after 12 weeks)

Method of measurement

blood test (Mg per deciliter)

Intervention groups

1

Description

The experiment group: Diabites, an herbal medicine for the treatment of diabetes, is provided in 750 mg capsules (licensed by Iranian Ministry of Health; produced and manufactured by Booalidaroo Company, Qom, Iran). The cases in the experiment group received Diabites 3 times a day, each time 1 capsule, in addition to the previously prescribed conventional (chemical) pharmaceuticals for 12 weeks.

Category

Treatment - Drugs

2

Description

The control group: The placebo (750 mg capsules similar to the interventional herbal medicine) was given to the control group cases 3 times a day, each time 1 capsule, in addition to the previously prescribed conventional (chemical) pharmaceuticals for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Qom

Full name of responsible person

Zahra Alsadat hosseini zefreh (Intern) and Maryam Rafiee(Intern)

Street address

Shahid Beheshti Hospital in Qom، Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

medical School، Qom University of Medical Sciences pardis، Qom

City

Qom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qom University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Qom University of Medical Sciences
Full name of responsible person
Mohammad Hosein Abd AlMohamadi
Street address
medical School، Qom University of Medical Sciences pardis، Qom
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences
Proportion provided by this source
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
Qom University of Medical Sciences
Full name of responsible person
Jamshid Vafaeemanesh
Position
Specialist Internal Medicine /Board of Qom University of Medical Sciences
Other areas of specialty/work
Street address
Medical School، Qom University of Medical Sciences Pardis، Qom
City
Qom
Postal code
3713649373
Phone
+98 25 3320 9071
Fax
Email
J.vafaeemanesh@muq.ac.irJvafaeemanesh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Jamshid Vafaeemanesh
Position
Spesialist Internal Medicine
Other areas of specialty/work
Street address
Medical school، Qom University of Medical Sciences Pardis، Qom
City
Qom
Postal code
3713649373
Phone
+98 25 3320 9071
Fax
Email
J.vafaeemanesh@muq.ac.irJvafaeemanesh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Jamshid Vafaeemanesh
Position
Spesialist Internal Medicine/Board of Qom University of Medical Sciences
Other areas of specialty/work
Street address
Medical school، Qom University of Medical Sciences Pardis،Qom
City
Qom
Postal code
3713649373
Phone
+98 25 3320 9071
Fax
Email
J.vafaeemanesh@muq.ac.irJvafaeemanesh@yahoo.com
Web page address

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