

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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 Diabetes (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 Diabetes 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 Vafaemanesh

Name of organization / entity

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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 sugar on 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

AgeFrom **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

lr.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: Diabetes, an herbal medicine for the treatment of diabetes, is provided in 750 mg capsules (licensed by Iranian Ministry of Health; produced and manufactured by Boosalidaroo Company, Qom, Iran). The cases in the experiment group received Diabetes 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 Vafaemanesh

Position

Specialist Internal Medicine /Board of Qom University
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Other areas of specialty/work

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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