Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparison of routine drug regime of blood glucose control with cinnamon and routine drug regime with placebo on FBS and Hb1AC in patients with non insulin dependent diabetes; A double blind randomized controlled clinical trial

Protocol summary

Summary

The aim of this clinical trial is comparison of routine drug regime of blood glucose control with cinnamon and routine drug regime with placebo on FBS and Hb1AC in patients with non insulin dependent diabetes that 138 patients referred to diabetes clinic of Valiasr hospital Birjand who meet the inclusion criteria and willing to cooperate in the study selected by convince sampling and assigned in two experimental (69 people) and control groups (69 people) based on randomized blocking allocation. 5 ml of 8 hours of fasting, venous blood from all patients sent to the Central Laboratory University and fasting blood glucose and serum levels of hemoglobin A1C measured by biochemical and HBLC methods respectively. In order to control blood glucose, all patients receive the routine treatment of diabetes based on approved protocol treatments. Besides that, experimental group given three capsules of 500 mg Cinnamon per day before breakfast, lunch and dinner for 90 days. In control group, samples receive three vitamin C capsules as placebo daily that their shape, size and color were similar to the capsules of the intervention group. After the drug administration (90th day), the level of fasting blood glucose and serum levels of hemoglobin A1C measured in the same condition while patients and physicians responsible for collecting data informed about the treatment type.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100230098N1**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology affairs of Birjand University of Medical Sciences (BUMS)

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of routine drug regime of blood glucose control with cinnamon and routine drug regime with placebo on FBS and Hb1AC in patients with non insulin dependent diabetes; A double blind randomized

controlled clinical trial

Public title
The effect of cinnamon on the level of FBS and Hb1AC in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: type II non-insulin dependent diabetes, blood levels of hemoglobin A1C between 6.5 and 7.5, desire to participate in the study. Exclusion criteria: not regular referring to diabetes control center, hemolytic anemia and thalassemia diseases, recent infusion of blood, uremia, allergy to cinnamon, kidney, liver and parathyroid diseases and intestinal problems, pregnancy, lactation, drug intolerance, signs of allergy to cinnamon, taking insulin, unexpected events and death
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **138**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Ghafari street
City
Birjand
Postal code
Approval date
2014-11-30, 1393/09/09
Ethics committee reference number
1393/09-08

Health conditions studied

1

Description of health condition studied
Non-insulin-dependent diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting glucose levels
Timepoint
Before intervention and 90 days after taking medication
Method of measurement
Blood sampling and determination of fasting glucose levels by enzymatic method

2

Description
Hemoglobin A1C
Timepoint
Before intervention and 90 days after taking medication
Method of measurement
Blood sampling and determination of the glycosylated hemoglobin by HPLC method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine treatment of diabetes to control blood sugar under approved therapy protocols, patients will receive three500 mg capsules of cinnamon daily before breakfast, lunch and dinner.
Category
Treatment - Drugs

2

Description
Control group: In addition to routine treatment of diabetes to control blood sugar under approved therapy protocols, samples will receive daily three vitamin C capsules as placebo that their shape, size and color are similar to the capsules of the intervention group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes clinic of Valiasr Hospital Birjand
Full name of responsible person
Vajehollah Raeesi
Street address
Valiasr hospital, Ghafari street, Birjand
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Birjand University of Medical Sciences
Full name of responsible person
Gholamreza Sharifzadeh
Street address
Vice chancellor for research, Birjand University of Medical Sciences, Ghafari street
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Birjand
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, Birjand 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
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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