

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

###### Name

Azadeh Zahedifar

###### Name of organization / entity

Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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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 three 500 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

**City**

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**

Birjand University of Medical Sciences

**Full name of responsible person**

Azadeh zahedifar

**Position**

Resident of internal medicine

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

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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*