

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Study of the effect of cinnamon on blood glucose levels and lipid profiles of Type II Diabetes Patients

#### Protocol summary

##### Study aim

Determination of effect of cinnamon on blood glucose and fat profiles of type 2 diabetes patients.

##### Design

In this study, 60 eligible patients with type 2 diabetes referring to diabetes centers of Zahedan University of Medical Sciences are selected. The participants are randomly divided into two groups of intervention and one control group. For blindness, each participant is assigned a code.

##### Settings and conduct

This study is a single-step, double blind, with control group clinical trial. It will be done by simple sampling method with Random allocation and will be conducted on 60 Patients with type 2 diabetes who are referred to diabetes Clinic of Zahedan University of Medical Sciences. None of the patients will be informed about which group they are in. People who give medicine to patients, they will not be aware of the type of drug or group of patients. Persons who collect the data, they will also be blind to the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are following: The minimum duration of having diabetes mellitus should be five years. The range of FBS should be 160-400 mg/dl. Glycosylated hemoglobin should be upper 7%. The age range should be 40 - 60 years old. The patient has metformin to control his blood glucose. Exclusion criteria are following: The patient has insulin therapy. The patient has other anti-glucose drugs or herbal medicines. The patient is pregnant / the patient is lactating mothers. The patient has allergy to cinnamon. The patient has nephropathy, hepatopathy or gastroenteropathy. The patient has not willing to continue the study. The patient has anti-diabetes drugs changes.

##### Intervention groups

In this study, the subjects will be randomly divided into two intervention groups and one control group. One intervention group will receive 2 grams and another 4

grams per day of cinnamon powder. The control group receives a placebo.

##### Main outcome variables

In this study, the effect of cinnamon on insulin resistance, glycosylated hemoglobin, cholesterol, triglyceride, HDL and LDL will be measured.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170130032293N4**

Registration date: **2018-03-13, 1396/12/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-13, 1396/12/22**

Update count: **0**

##### Registration date

2018-03-13, 1396/12/22

##### Registrant information

##### Name

Hamed Sarani

##### Name of organization / entity

Zahedan University Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3344 2481

##### Email address

sarani@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Study of the effect of cinnamon on blood glucose levels and lipid profiles of Type II Diabetes Patients

**Public title**  
Effect of cinnamon on blood glucose and lipid of Type II Diabetes.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The minimum duration of having diabetes mellitus should be five years The range of FBS should be 400-160 mg/dl Glycosylated hemoglobin should be upper 7% The age range should be 40 - 60 years old The patient only uses metformin to control his blood glucose  
**Exclusion criteria:**  
The patient has insulin therapy. The patient has other anti\_glucose drugs or herbal medicines. The patient is pregnant /the patient is lactating mothers. The patient has allergy to cinnamon. The patient has nephropathy, hepatopathy or gastroentropathy. The patient has not willing to continue the study

**Age**  
From **40 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, 120 cards will be prepared in three colors: green, blue, and white (40 for each color). Then, patients who have criteria for entering the study are selected in a Convenience method. To allocate a group, each patient picks up one of the cards in the box and based on the color of the card, in one of the groups of cinnamon 2, cinnamon 4 or control will be placed. The card is returned to the box twice. Cards will be shuffled one more time for every patient. Sampling will be done similarly until the completion of groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
This study is a double-blind study. None of the patients

will be informed about which group they are in. People who give medicine to patients, they will not be aware of the type of drug or group of patients. Persons who collect the data, they will also be blind to the groups, but the researcher and final analyst will not be blind.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics Committee of Zahedan Medical University of Sciences

**Street address**

Zahedan University Medical Sciences, Hesabi Sq, University Street, Zahedan

**City**

zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Approval date**

2017-08-29, 1396/06/07

**Ethics committee reference number**

IR.ZAUMS.oth.REC.1396.6

## Health conditions studied

### 1

**Description of health condition studied**

Type 2 diabetes mellitus

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

## Primary outcomes

### 1

**Description**

Fasting blood sugar levels In milligrams per deciliter, will be measured.

**Timepoint**

Fast Blood Sugar will be measured four times; 1- Before intervention, 2- Four weeks after the intervention, 3- Eight weeks after the intervention; 4- 12 weeks after the intervention.

**Method of measurement**

After about ten hours of fasting, 5 cc venous blood

sample from each research unit will be taken. The blood serum is then isolated and glucose level will be measured by glucose oxidase method.

## 2

### **Description**

The amount of glycosylated hemoglobin, which shows the average amount of blood sugar in the last three months

### **Timepoint**

This variable will be measured four times; 1- Before intervention, 2- Four weeks after the intervention, 3- Eight weeks after the intervention; 4- 12 weeks after the intervention.

### **Method of measurement**

After about ten hours of fasting, 5 cc venous blood sample from each research unit will be taken. The blood serum is then isolated and Glycosylated hemoglobin by enzymatic calorimetric method and Using commercial bionic kits, Tehran Pars Azmoon Co. is will be measured.

## 3

### **Description**

Serum insulin, blood serum insulin levels are measured.

### **Timepoint**

This variable will be measured four times; 1- Before intervention, 2- Four weeks after the intervention, 3- Eight weeks after the intervention; 4- 12 weeks after the intervention.

### **Method of measurement**

After about ten hours of fasting, 5 cc venous blood sample from each research unit will be taken. The blood serum is then isolated and insulin level will be measured by the chemiluminescence method.

## 4

### **Description**

Insulin resistance

### **Timepoint**

This variable will be measured four times; 1- Before intervention, 2- Four weeks after the intervention, 3- Eight weeks after the intervention; 4- 12 weeks after the intervention.

### **Method of measurement**

After about ten hours of fasting, 5 cc venous blood sample from each research unit will be taken. The blood serum is then isolated and glucose is evaluated by glucose oxidase and insulin by the chemiluminescence method and then Insulin resistance will be measured using the Homeostatic Model Assessment Insulin Resistance (HOMA-IR).

## 5

### **Description**

Blood lipid levels include Cholesterol, HDL, LDL and Triglyceride.

### **Timepoint**

This variables will be measured four times; 1- Before intervention, 2- Four weeks after the intervention, 3-

Eight weeks after the intervention; 4- 12 weeks after the intervention.

### **Method of measurement**

After ten hours of fasting, 5 cc venous blood sample from each research unit before the intervention, weeks 4, 8 and 12 after the intervention are taken. The blood serum is then isolated and Cholesterol, HDL, LDL, and triglycerides by enzymatic calorimetric method and Using commercial bionic kits, Tehran Pars Azmoon Co. is will be measured.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The purpose and method of work will be explained for all patients. It is also recommended to patients do not use cinnamon 15 days before and during the study. Written consent will be taken, One intervention group will receive 2 grams and another 4 grams per day of cinnamon powder. The control group receives a placebo. To prepare cinnamon, the cinnamon shell will be turned into powder by an electric mill. Cinnamon powder will be packed in capsules of the same color and shape and size. To the control group, similar capsules containing cellulose will be given. Each participant will receive 4 capsules daily for 8 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Diabetes Clinic of Zahedan University of Medical Sciences

##### **Full name of responsible person**

parvaneh sarani ali abadi

##### **Street address**

Zahedan University Medical Sciences, Hesabi Sq, University Street, Zahedan

##### **City**

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##### **Email**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

fereshteh dahmardeh

**Street address**

Iran - Zahedan - University Street - Islamic Azad  
University of Zahedan - Faculty of Medical Sciences

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**Province**

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**Email**

research1@iazah.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

parvaneh sarani ali abadi

**Position**

faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Latest degree**

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

faculty member

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

hamedsarani@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available