

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Cinnamon (Cinnamon chromium) powder on body composition and chemical bio-markers of diabetic type 2 patients based no the body mass index.

#### Protocol summary

##### Summary

This study aimed to determine the effect of Cinnamon (Cinnamon chromium) powder on body composition and chemical bio-markers of diabetic patients type 2 divided to body mass index, with the hypothesis that cinnamon is more effective in diabetic patients with high body mass index than those with a low body mass index. Among diabetic patients of Yazd diabetic center, 120 patients with type 2 diabetes who did not have any complication of diabetes with a BMI between 18.5 and 40 will be enrolled. For all patients physical activity questionnaire, food frequency and mezaj questionnaires will be completed. fasting blood glucose ,HB (A1C), cholesterol, triglycerides, LDL and HDL and 2 hours post prandial glucose will be measured. Anthropometric factors including body weight, body mass index, muscle mass percentage, fat mass percentage will be measured by digital scale (OMRON BF511). All patients will be randomly divided into two groups case group : treated with 500 mg capsules of cinnamon twice a day, The control group receive placebo capsules twice a day. Patients and researcher will be blinded to allocation. The treatment period is three months and all biochemical and anthropometric parameters will be measured at the end of the study. All data will entered into SPSS software and analyzed in two groups with high and low body mass index.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017031133015N1**

Registration date: **2017-04-21, 1396/02/01**

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

Last update:

Update count: **0**

##### Registration date

2017-04-21, 1396/02/01

##### Registrant information

###### Name

Roghayeh Zare

###### Name of organization / entity

Shiraz University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3725 3242

###### Email address

stud5529941941@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-07-06, 1396/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Cinnamon (Cinnamon chromium) powder on body composition and chemical bio-markers of diabetic type 2 patients based no the body mass index.

##### Public title

Effect of Cinnamon on diabetes

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: informed consent to participate in the study; patients with type 2 diabetes; Patients who only use oral medications to control their blood sugar ;Lack of disease or complications of diabetes ; body mass index between 18.5 and 40 ; Patients with a fasting blood glucose between 126 to 250 milligrams per deciliter .

Exclusion criteria: People who change during the study their treatment to insulin ; Lack of regular use of oral capsules (including cinnamon or placebo) ;sensitivity to other diseases during the study drug ; Cancel participate on the study; patients with a BMI of less than 18.5 (thin) and patients with a body mass index over 40 (morbid obese)

### **Age**

From **20 years** old to **80 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **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**

Shiraz University of Medical Sciences, Shiraz, Iran

##### **Street address**

Zand avenue, Shiraz, Iran

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2017-01-22, 1395/11/03

#### **Ethics committee reference number**

IR.SUMS.REC.1395.176

## **Health conditions studied**

### 1

#### **Description of health condition studied**

diabetes

#### **ICD-10 code**

E11

#### **ICD-10 code description**

typell,Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

Fasting blood glucose

#### **Timepoint**

at onset and after 3 months

#### **Method of measurement**

blood sample

### 2

#### **Description**

Glycosylated Hemoglobine

#### **Timepoint**

at onset and after 3 months

#### **Method of measurement**

blood sample

### 3

#### **Description**

2hours post parandial glougose

#### **Timepoint**

at onset and after 3 months

#### **Method of measurement**

blood sample

## **Secondary outcomes**

### 1

#### **Description**

mezaj

#### **Timepoint**

onset

#### **Method of measurement**

questionary

### 2

#### **Description**

body activity

#### **Timepoint**

onset

#### **Method of measurement**

questionary

### 3

#### **Description**

calery intake

#### **Timepoint**

onset  
**Method of measurement**  
food frequency questionnaire

#### 4

**Description**  
triglyceride  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
blood sample

#### 5

**Description**  
colstrol  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
blood sample

#### 6

**Description**  
weight  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
digital scale (OMRON BF511)

#### 7

**Description**  
body mass indwx  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
digital scale (OMRON BF511)

#### 8

**Description**  
fat mass percentage  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
digital scale (OMRON BF511)

#### 9

**Description**  
muscle mass index  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
digital scale (OMRON BF511)

#### 10

**Description**  
hdl  
**Timepoint**  
at onset and after 3 months

**Method of measurement**  
blood sample

#### 11

**Description**  
ldl  
**Timepoint**  
at onset and after 3 months  
**Method of measurement**  
blood sample

### Intervention groups

#### 1

**Description**  
cinnamon powder cap 500 mg ,BD,for three months  
**Category**  
Treatment - Drugs

#### 2

**Description**  
placebo,cap 500 mg, BD , for three months  
**Category**  
Placebo

### Recruitment centers

#### 1

**Recruitment center**  
**Name of recruitment center**  
khani Diabetes Center  
**Full name of responsible person**  
Roghayeh Zare  
**Street address**  
khani Diabetes Center ,Shahid Sadoghi Ave,Yazd,Iran  
**City**  
Yazd

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Seyed Basir Hashemi  
**Street address**  
Vice-Chancellor for Research, Shiraz University of  
Medical Sciences, Zand Blvd., Shiraz, Iran Postal  
Code; 71345-1978  
**City**  
Shiraz  
**Grant name**  
**Grant code / Reference number**  
11229  
**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz Medical University

**Full name of responsible person**

Roghayeh Zare

**Position**

PHs Traditional Persian Medicine

**Other areas of specialty/work**

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**Full name of responsible person**

Roghayeh Zare

**Position**

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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*