

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)

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+98 35 3725 3242

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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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Person responsible for scientific inquiries

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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