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 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 gastroenrtopathy. 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 Siences

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 gastroenrtopathy. 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 serums 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 serums 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 serums 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 serums 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 serums 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

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3113 5570

Fax

+98 54 3113 5570

Email

spsarani@yahoo.com

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
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743545
Phone
+98 54 3342 9720
Fax
+98 54 3342 9723
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
Street address
University Street
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743545
Phone
+98 54 3113 5570
Fax
+98 54 3113 5570
Email
spsarani@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
parvaneh sarani ali abdi
Position
faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
University Street
City
ZAHEDAN
Province
Sistan-va-Balouchestan
Postal code
9816743545
Phone
+98 54 3113 5570
Fax
+98 54 3113 5570
Email
spsarani@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
hamed sarani
Position
faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
university Street
City
ZAHEDAN
Province
Sistan-va-Balouchestan
Postal code
9816913396
Phone
+98 54 3344 2482
Fax

+98 54 3344 2481

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