Clinical Trial Protocol
Iranian Registry of Clinical Trials
23 Nov 2021

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 metformin to control his blood glucose. Exclusion criteria are following: The patient has metformin to control his blood glucose. Exclusion criteria are following: The patient has metformin to control his blood glucose. Exclusion criteria are following: The patient has metformin to control his blood glucose.

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
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 about 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

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

+98 54 3344 2481
Email
hamedsarani@gmail.com