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 gastroentopathy. 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)
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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 will be 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

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

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Sponsors / Funding sources

1

Sponsor
  Name of organization / entity
  Islamic Azad University
  Full name of responsible person
  fereshteh dahmardeh

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

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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 abdi

Position
  faculty member

Latest degree
  Master

Other areas of specialty/work
  Nursery

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Other areas of specialty/work
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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