Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2021

Assessment of cinnamon effects on advanced glycation end products, plasma vascular and systematic inflammation factors, antioxidant status, NF-kB and Sirtuin1 activity in mononuclear cells in type 2 diabetic patients

Protocol summary

Summary

The main objective of the project "Determination of cinnamon effects on advanced glycation end products, plasma vascular and systematic inflammation factors, antioxidant status, NF-kB and Sirtuin 1 activity in mononuclear cells in type 2 diabetic patients". This clinical trial is a randomized, double-blind and placebo-controlled. Patients with type II diabetes clinics and medical centers in Tehran referred to the relevant elected in accordance with the inclusion and exclusion criteria. The sample size was estimated for each group of 20 patients, including 10% loss, 22 patients in each group and a total of 44 patients, respectively. In this study, patients with type II diabetes who are eligible to study the subject, objectives and methodology is explained study, If you wish to participate in this study are patients informed consent is obtained. The patients were divided into 2 groups using random numbers table. In order to execute a double-blind study, at baseline set by anyone other than the researchers encoded packets containing the capsules to lack of knowledge of the capsules received by each group is maintained. The patients in the supplement group capsules of cinnamon, cinnamon supplement capsules at baseline package is for 8 weeks. The patients in the supplement group cinnamon capsules daily 3 grams of cinnamon supplementation (capsules 1 gr cinnamon, 3 times per day) during the study receive 8 weeks. Patients in the control group at baseline capsules packages placebo (microcrystalline cellulose) that are similar to cinnamon supplement capsules for 8 weeks is and the patient is asked to capsules 1 gr microcristalin cellulose, 3 times per day, use .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061128392N1**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Behrouz Talaei

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

National Nutrition & Food Technology Research Institute (NNFTRI) (Shahid Beheshti University of Medical Sciences Faculty of Nutrition Sciences and food technology) and Research Institute for Endocrine Sciences Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of cinnamon effects on advanced glycation end products, plasma vascular and systematic inflammation factors, antioxidant status, NF-kB and Sirtuin1 activity in mononuclear cells in type 2 diabetic patients

Public title
Assessment of cinnamon effects in type 2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : Having type 2 diabetes for at least 10 years؛ FBS <180 and 2 h-blood-sugar <250 mg/dl؛ no pregnancy or lactation؛ no autoimmune disorder؛ without any thyroid , kidney , CVD diseases, thyroid and chronic inflammatory diseases, peptic ulcer and infection؛ no regular consumption of cinnamon or other herbal drugs؛ no sensitivity People who are just using the pills (not insulin)؛ your diabetes control cinnamon؛ body mass index (BMI) <30 kg/m ؛ Age between 70-25 years. Exclusion criteria : No observation of research protocol (no consumption of more than 20% of the capsules)؛ any sensitivity due to cinnamon consumption reported by the patient or noticed after the outset of the study؛ consumption of alcohol or narcotic drugs؛ and any variation in patients' routine treatment according to physicians' resolution (i.e., variation in type and dose of the drugs to be consumed, and treatment with insulin)؛ Pregnancy during the study.
Age
From **70 years** old to **25 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **44**
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
National Nutrition & Food Technology Research Institute (NNFTRI)
Street address
NO 7, St. shahid hafizi, West town, Tehran
City
Tehran
Postal code
1981619573
Approval date
2016-03-12, 1394/12/22
Ethics committee reference number
IR.SBMU.nnftri.Rec.1394.36

Health conditions studied

1

Description of health condition studied
DIABETES
ICD-10 code
E11.9
ICD-10 code description
Non-insulin-dependent diabetes mellitus without complications

Primary outcomes

1

Description
Sirtuin Activity 1
Timepoint
Before and after the intervention.
Method of measurement
ng/ml

2

Description
Fasting insulin
Timepoint
Before and after the intervention
Method of measurement
mU/L

3

Description
HOMA-IR
Timepoint
Before and after the intervention
Method of measurement

%

4

Description
Fasting plasma glucose
Timepoint
Before and after the intervention
Method of measurement
mg/dl

5

Description
Carboxymethyl-lysine plasma
Timepoint
Before and after the intervention
Method of measurement
ng/ml

6

Description
Hb A1c
Timepoint
Before and after the intervention
Method of measurement
%

7

Description
The activity NF-kB
Timepoint
Before and after the intervention
Method of measurement
ng/ml

8

Description
VCAM-1
Timepoint
Before and after the intervention
Method of measurement
ng/ml

9

Description
hs-CRP
Timepoint
Before and after the intervention
Method of measurement
ng/ml

10

Description
IL-6
Timepoint
Before and after the intervention
Method of measurement
ng/L

11

Description
TNF
Timepoint
Before and after the intervention
Method of measurement
ng/L

12

Description
ICAM-1
Timepoint
Before and after the intervention
Method of measurement
ng/ml

Secondary outcomes

1

Description
Vitamin E diet
Timepoint
Before and after the intervention
Method of measurement
mg/day

2

Description
MUFA
Timepoint
Before and after the intervention
Method of measurement
gr/day

3

Description
PUFA
Timepoint
Before and after the intervention
Method of measurement
gr/day

4

Description
Salt diet
Timepoint
Before and after the intervention
Method of measurement
gr/day

5

Description
SAFA
Timepoint
Before and after the intervention.
Method of measurement

gr/day

6

Description
Fat Diet
Timepoint
Before and after the intervention.
Method of measurement
gr/day

7

Description
Cholesterol diet
Timepoint
Before and after the intervention
Method of measurement
mg/day

8

Description
Dietary fiber
Timepoint
Before and after the intervention
Method of measurement
mg/day

9

Description
Protein Diet
Timepoint
Before and after the intervention
Method of measurement
gr/day

10

Description
BMI
Timepoint
Before and after the intervention
Method of measurement
Kilograms per square meter

11

Description
Carb Diet
Timepoint
Before and after the intervention
Method of measurement
gr/day

12

Description
Total dietary energy
Timepoint
Before and after the intervention
Method of measurement
Kcal/day

13

Description
Vitamin C diet
Timepoint
Before and after the intervention
Method of measurement
mg/day

14

Description
Selenium diet
Timepoint
Before and after the intervention
Method of measurement
mcg/day

Intervention groups

1

Description
The intervention group: capsules 1 gr Cinnamon, 3 times per day, for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: capsules 1 gr microcristalin cellulose, 3 times per day, for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Erfan Hospital
Full name of responsible person
Behrouz Talaei
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition & Food Technology Research Institute (NNFTRI)
Full name of responsible person
DR.Parvin Mirmiran
Street address
NO 7, St. shahid hafiz, West town, Tehran
City

Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Nutrition & Food Technology Research Institute (NNFTRI)
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences
Full name of responsible person
dr.Parvin Mirmiran
Street address
Next to Taleghani Hospital, Velenjak
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences
Proportion provided by this source
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
Shahid Beheshti University of Medical Sciences Faculty of Nutrition Sciences and food technology
Full name of responsible person
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Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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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