

# 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 microcrystalline 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)

##### **Phone**

+98 912 558 1202

##### **Email address**

b\_talaei@nnftri.ac.ir

##### **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 microcrystalline 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**

Behrouz Talaei

**Position**

PhD Student, Nutrition Sciences

**Other areas of specialty/work**

**Street address**

NO 7, St. shahid hafizi, West town, Tehran

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**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

dr.Parvin Mirmiran

**Position**

PhD Nutrition

**Other areas of specialty/work**

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B\_TALAEI@HOTMAIL.COM ,  
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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Behrouz Talaei

**Position**

PhD Student, Nutrition Sciences

**Other areas of specialty/work**

**Street address**

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**Web page address**

**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*