

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### Determination of the effect of broccoli sprouts on biochemical markers of oxidative stress in serum in patients with type 2 diabetes

#### Protocol summary

##### Summary

Broccoli sprouts have shown beneficial effects on pathological conditions such as cardiovascular diseases. In the present study we aimed to examine the effect of consumption of broccoli sprouts on biomarkers of oxidative stress in patients with type 2 diabetes. Eighty patients (40 in each group) with type 2 diabetes will be recruited and randomly divided into two groups. Blood samples and 24-h dietary recall will be taken before intervention. Then, for two months participants in one group will receive 10 mg dried broccoli sprouts per day, and another group will receive the same amount of corn starch as placebo. At the end of the intervention, blood samples will be taken. Total antioxidant capacity, total oxidant status, malondialdehyde, and lipid peroxides will be measured in serum. Data will be analyzed with SPSS version 16.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013070810190N3**

Registration date: **2013-07-17, 1392/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-07-17, 1392/04/26

##### Registrant information

###### Name

Masoumeh Akhlaghi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1725 7288

##### Email address

akhlaghi\_m@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-01-31, 1392/11/11

##### Expected recruitment end date

2014-09-30, 1393/07/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of the effect of broccoli sprouts on biochemical markers of oxidative stress in serum in patients with type 2 diabetes

##### Public title

Effect of broccoli sprouts on markers of oxidation in type 2 diabetes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion/exclusion: Inclusion: Patients with type 2 diabetes with at least 3 years from the onset of the disease. Exclusion criteria: Insulin therapy, taking especial medications such as hormones, hypoglycemic agents, and lipid lowering medications, vitamin and iron supplements, vitamin K antagonists, those with nephropathy, neuropathy, and cardiovascular disease, liver disease, cancers, autoimmune and inflammatory diseases, pregnant and lactating women, smokers, and those on especial diets, and those who make major

changes in their diet during intervention.

#### **Age**

From **30 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Shiraz University of Medical Sciences

###### **Street address**

Zand Blvd

###### **City**

Shiraz

###### **Postal code**

##### **Approval date**

2012-09-05, 1391/06/15

##### **Ethics committee reference number**

CT-9223

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Type 2 diabetes

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Total antioxidant capacity

##### **Timepoint**

At the beginning of study and at the end of intervention

#### **Method of measurement**

Biochemical analysis

#### **2**

##### **Description**

Total oxidant status

##### **Timepoint**

At the beginning of study and at the end of intervention

##### **Method of measurement**

Biochemical analysis

#### **3**

##### **Description**

Malondialdehyde

##### **Timepoint**

At the beginning of study and at the end of intervention

##### **Method of measurement**

Biochemical analysis

#### **4**

##### **Description**

Lipid peroxides

##### **Timepoint**

At the beginning of study and at the end of intervention

##### **Method of measurement**

Biochemical analysis

### **Secondary outcomes**

#### **1**

##### **Description**

BMI

##### **Timepoint**

At the beginning and at the end of study

##### **Method of measurement**

Weighing

### **Intervention groups**

#### **1**

##### **Description**

10 g per day dried broccoli sprouts. Broccoli sprouts are an agricultural product cultivated by Agriculture Division in Shiraz University. Sprouts are consumed once per day for two months. Participants are asked to consume the sprouts with yogurt or other dishes.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

10 g/day corn starch colored with spinach powder. Participants are asked to consume the starch with yogurt or other dishes.

##### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Physicians' offices

**Full name of responsible person**

**Street address**

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research deputy of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Reza Hatam

**Street address**

Central Building-Zand Street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research deputy of Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Masoumeh Akhlaghi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Razi Blvd, College of Health and Nutrition

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*