

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Determination of the effect of broccoli sprouts on pro- and anti-inflammatory markers in serum of 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 pro-inflammatory and anti-inflammatory markers 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, serum will be separated and examined for detection of C-reactive protein, tumor necrosis alpha, and interleukin-6. Data will be analyzed with SPSS version 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070810190N4**

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 pro- and anti-inflammatory markers in serum of patients with type 2 diabetes

Public title

Determination of the effect of broccoli sprouts on inflammation in patients with diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Patients with type 2 diabetes with at least 3 years from the onset of the disease. Exclusion: 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**

2012-09-06, 1391/06/16

Ethics committee reference number

CT-91-6224

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

C reactive protein

Timepoint

At the beginning of study and at the end of intervention

Method of measurement

Biochemical analysis

2**Description**

Tumor necrosis factor-alpha

Timepoint

At the beginning of study and at the end of intervention

Method of measurement

Biochemical analysis

3**Description**

Interleukin-6

Timepoint

At the beginning of study and at the end of intervention

Method of measurement

Biochemical analysis

Secondary outcomes**1****Description**

Body mass index

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. 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

City
Shiraz

Postal code

Phone
+98 71 1725 7288

Fax

Email
akhlaghi_m@sums.ac.ir

Web page address

Person responsible for scientific

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

City
Shiraz

Postal code

Phone
+98 71 1725 7288

Fax

Email
akhlaghi_m@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Masoumeh Akhlaghi

Position
Assistant Professor

Other areas of specialty/work

Street address
School of Health and Nutrition- Razi Blvd

City
Shiraz

Postal code

Phone
+98 71 1725 7288

Fax

Email
akhlaghi_m@sums.ac.ir

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