

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

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inquiries

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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