

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

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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