

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effects of broccoli sprouts powder supplementation on clinical and biochemical parameters in metabolic syndrome patients with positive Helicobacter Pylori test

Protocol summary

Summary

Metabolic syndrome is a branch of the metabolic disorders including obesity, impaired lipid metabolism, glucose intolerance, insulin resistance and hypertension that is associated with an increased risk of developing cardiovascular disease and type 2 diabetes. Recent studies show that Helicobacter pylori infection is one of the risk factors of metabolic syndrome, type 2 diabetes and cardiovascular diseases. Studies have shown that treatment of H. pylori infection in patients with metabolic syndrome cause to improvement of insulin resistance and risk factors of cardiovascular disease. This study investigated the effect of supplementation with broccoli sprouts powder as compared to standard triple therapy in patients with metabolic syndrome or type 2 diabetic patients with Helicobacter pylori infection. Stool samples are obtained to detect H. pylori stool antigen test. Patients with H. pylori infection are randomized to one of three groups, the standard triple therapy (STT), broccoli sprouts powder (BSP), or BSP+STT. STT group receive antibiotic therapy for 2 weeks. BSP group get 6 grams broccoli sprouts powder daily, and STT+BSP group receive combination of standard triple therapy and broccoli sprouts. At the beginning and one months after the treatment, stool antigen test and biochemical analysis, and urea breath test at end of the study will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111081640N6**
Registration date: **2011-11-27, 1390/09/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-27, 1390/09/06

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

mirmiran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Endocrine Sciences, Shahid Beheshti Medical Sciences University

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of broccoli sprouts powder supplementation on clinical and biochemical parameters in metabolic syndrome patients with positive Helicobacter Pylori test

Public title

Effects of broccoli sprouts powder supplementation on clinical and biochemical parameters in metabolic syndrome patients with positive Helicobacter Pylori test

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with metabolic syndrom according to IDF; patients with positive Helicobacter Pylori test according to stool antigene test. Exclusion criteria: pregnant or breastfeeding women; smoker or alcohol or other drugs abusers; patients receiving vitamin K antagonists, steroid hormones and antioxidant supplement. patients with diabetes,Cardiovascular ,chronic liver, respiratory, chronic renal disease; patients with chronic or acute inflammatory diseases.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics committee, Research Institute for Endocrine Sciences, Shahid Beheshti Medical Sciences Unive

Street address

Tehran, Research Institute for Endocrine Sciences,24, Parvaneh St,Chamran Exxp,Tehran

City

Tehran

Postal code

Approval date

2011-08-02, 1390/05/11

Ethics committee reference number

357EC

Health conditions studied

1

Description of health condition studied

metabolic syndrom

ICD-10 code

E90

ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

Primary outcomes

1

Description

Decrease of H.Pylori infection

Timepoint

6 weeks

Method of measurement

Biochemical analysis

2

Description

Improvement of metabolic syndrome risk factors

Timepoint

6 weeks

Method of measurement

Biochemical analysis

3

Description

Improvement of oxidative stress

Timepoint

6 weeks

Method of measurement

Biochemical analysis

Secondary outcomes

1

Description

Improvement of metabolic syndrom criteria

Timepoint

6 weeks

Method of measurement

Biochemical analysis

2

Description

Improvement of metabolic syndrom criteria

Timepoint

6 weeks

Method of measurement

biochemical analysis

Intervention groups

1

Description

-broccoli sprouts powder 6 g/day

Category

Placebo

2

Description

corn starch 6 g/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Endocrine Sciences, Shahid
Beheshti Medical Sciences University

Full name of responsible person

Pavin Mirmiran

Street address

Tehran, Research Institute for Endocrine Sciences, 24
Parvaneh St, Yaman St, Chamran Exp

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid
Beheshti Medical Sciences University

Full name of responsible person

Parvin Mirmiran

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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 Medical Sciences University

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

Research Institute for Endocrine Sciences, Shahid
Beheshti Medical Sciences University

Full name of responsible person

Parvin Mirmiran

Position

Ph.D of Nutrition Sciences-

Other areas of specialty/work

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Beheshti Medical Sciences University

Full name of responsible person

Zahra Bahadoran

Position

Msc student of Nutrition Sciences

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty