

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

To study the effect of purslane seeds consumption on the indexes of metabolic syndrome in women with metabolic syndrome.

Protocol summary

Summary

Design study: Single blinded, randomized controlled clinical trial. The purpose of the study: The effect of purslane seeds consumption on the indexes of metabolic syndrome in women with metabolic syndrome. Method of study: From Middle-aged women 30-59 years referred to 22 Bahman Health Center of Bam City 64 persons with metabolic syndrome (having three criteria of characteristics: high triglycerides of 150 mg/dl, HDL less than 50 mg/dl, FBS more than 100 mg/dl, waist circumference more than 80 cm, blood pressure above 130/85) assigned randomly in two control and intervention groups with sample size 32 persons. Randomization will be done by random numbers table. The beginning and end the study Anthropometric measurement for them (height, weight, waist circumference, BMI) will be done and be asked them visit to reference laboratory for assessed blood test: FBS, TC, TG, HDL, LDL(12 week after beginning study). Control group will receive 150 gr of low fat yoghurt and to intervention group will be given 5 gr purslane seeds 2 times and 150 gr of low fat yoghurt. Also blood pressure will be measured per Recourse at least 4 times. From participants will be asked that don't change their physical activities, diet, drugs and lifestyle in during this study. The results will comparison with together the end of the study. The aim of doing this study is determine the effect of the purslane powder on metabolic syndrome in women and help to cure that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111810826N20**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences .

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To study the effect of purslane seeds consumption on the indexes of metabolic syndrome in women with metabolic syndrome.

Public title

The effect of purslane seeds consumption on metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women who have three indicators of Indices metabolic syndrome; Having written informed consent; Constant treatment for 3 months; Age between 30 - 59 years. Exclusion criteria: Pregnancy or Breastfeeding; Any skin or Digestive allergy to purslane; Have any underlying disease (autoimmune diseases, gastrointestinal, live, thyroid, unstable heart disease).

Age

From **30 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Shahid Sadoughi University of Medical Sciences

Street address

Yazd - 5 km road Bafgh - School of International Campus

City

Yazd

Postal code

8944157963

Approval date

2016-08-14, 1395/05/24

Ethics committee reference number

17/1/111126/ب- IR.SSU.MEDICINE.REC.1395.128

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E78.8

ICD-10 code description

Other disorders of lipoprotein metabolism

Primary outcomes

1

Description

FBS

Timepoint

Before the start of the study and 12 weeks after intervention

Method of measurement

blood biochemical test

2

Description

blood pressure

Timepoint

before ,during and 12 weeks after starting intervention

Method of measurement

Mercury Barometer

3

Description

HDL

Timepoint

Before the start of the study and 12 weeks after intervention

Method of measurement

blood biochemical test

4

Description

TG

Timepoint

Before the start of the study and 12 weeks after intervention

Method of measurement

blood biochemical test

5

Description

Waist

Timepoint

Before the start of the study and 12 weeks after intervention

Method of measurement

cm using meter

Secondary outcomes

1

Description

LDL

Timepoint

before and 12 weeks after starting intervention

Method of measurement

blood biochemical test

2

Description

TC

Timepoint

before and 12 weeks after starting intervention

Method of measurement

blood biochemical test

3

Description

Weight

Timepoint

before and 12 weeks after starting intervention

Method of measurement

digital scale

4

Description

Height

Timepoint

before and 12 weeks after starting intervention

Method of measurement

meter

5

Description

BMI

Timepoint

before and 12 weeks after starting intervention

Method of measurement

meter and digital scale

Intervention groups

1

Description

The consumption 5 gr purslane seed, 2 times a day with 150 gr low-fat yoghurt with lunch and dinner for 12 weeks

Category

Other

2

Description

The control group received only 150 gr low-fat yogurt with lunch and dinner for 12 weeks

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman

Full name of responsible person

Maryam Kamalaldini. Midwife

Street address

Takhti alley, Takhti Avenue, Bam

City

Bam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition And Food Security Research Center Shahid Sadoghi Yazd University Of Medical Sciences

Full name of responsible person

Azadeh Najarzadeh

Street address

Nutrition and Food Security Research Center, School of Public Health, Medical Campus, Shohadaye Gomnam Blvd, Alem Sq, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nutrition And Food Security Research Center Shahid Sadoghi Yazd 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

International Campus, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Maryam Papoli Baravati

Position

Ms student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Azadeh Najarzadeh

Position

PhD of Nutrition

Other areas of specialty/work

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Postgraduate Student

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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