Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

To study the effect of purslane seeds consumption on the indexs 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)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

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 indexs 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/پ- 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 ofter starting intervention

Method of measurement

blood biochemical test

2

Description

TC

Timepoint

before and 12 weeks ofter starting intervention

Method of measurement

blood biochemical test

3

Description

Weight

Timepoint

before and 12 weeks ofter starting intervention

Method of measurement

digital scale

4

Description

Height

Timepoint

before and 12 weeks ofter starting intervention

Method of measurement

meter

5

Description

BMI

Timepoint

before and 12 weeks ofter starting intervention

Method of measurement

meter and digital scale

Intervention groups

1

Description

The consumption 5 gr purslane seed, 2 times a day with 15o 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

Street address

Yazd- 5 km road Bafqh road, International Campus
City
Yazd
Postal code
8944157963
Phone
+98 35 4836 7634
Fax
Email
maryampapoli93@gmail.com
Web page address

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
Street address
5 km Bafq road, International Campus
City
Yazd
Postal code
8944157963
Phone
+98 35 4836 7634
Fax
Email
azadehnajarzadeh@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Maryam Papoli Baravati
Position
Postgraguate Student
Other areas of specialty/work
Street address
5 km Bafqh road, International Campus,Yazd, Iran
City
Yazd
Postal code
8944157963
Phone
+98 35 4836 7634
Fax
Email
maryampapoli93@gmail.com
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