Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effects of Portulaca oleracea Extract capsule on inflammatory biomarkers, lipid profile and serum glucose, anthropometric indices and blood pressure in adult with Metabolic syndrome for prevention of heart disease.

Protocol summary

Summary

People with metabolic syndrome according to the inclusion criteria were selected and randomly divided into 2 groups and control blood samples were taken, Height , weight, waist circumference and blood pressure were recorded, intervention group took purslane capsules for 2 months and the control group took placebo capsules. Experiments were repeated after 2 months, the results were analyzed using the spss software

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121920366N1**
Registration date: **2015-02-14, 1393/11/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name

Marjan Badakhanian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Isfahan University of Medical Sciencesand Research Center of Isfahan University of Medical Sciences

Expected recruitment start date

2014-04-06, 1393/01/17

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Portulaca oleracea Extract capsule on inflammatory biomarkers, lipid profile and serum glucose, anthropometric indices and blood pressure in adult with Metabolic syndrome for prevention of heart disease.

Public title

The Effects of Portulaca oleracea Extract capsule on inflammatory biomarkers, lipid profile and serum glucose, anthropometric indices and blood pressure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: persons suffering from obesity as defined by the IDF (WC≥ 102 in men) and have 2 signs of the 4 following symptoms, the metabolic syndrome was diagnosed. In this study, the characteristics of metabolic syndrome will be considered, if the criteria were the terms of this syndrome (having 2 of the first 4), other

criteria will be checked: 1-high blood pressure (systolic>130mhg and diastolic>85mmhg); 2-fasting blood glucose>100mg/dl; 3-TG>150mg/dl; 4-HDL<40mg/dl; -gender: male; no history of cancer, kidney, thyroid, diabetes, and anemia; lack of use of alcohol and drugs; no smoking history or drug allergy; no special diet; no change in medication in the last three months; lack of drugs that control blood sugar, lipid and blood pressure; no taking medications affecting inflammation, such as corticosteroids. Exclusion criteria: during the study , patients who lose their inclusion criteria, including smoking; suffering from diseases such as heart problems , kidney , thyroid and digestive disorders and lack of cooperation.

Age
From **27 years** old to **59 years** old

Gender
Male

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Making Purslane extract capsule: Purslane Confirmed in the Department of Pharmacognosy , Faculty of Pharmacy, then, 20 kg of plants dried in the shade , with 150 liters of ethanol with maceration method for 4 days extraction was repeated three times. The extract was filtered through filter paper using a rotary evaporator (Haydolf , Germany) under the pressure of a vacuum pump with a pressure of 10 mbar and a temperature of 40 ° C Was solved. The concentrated extract mixtured with anhydrous calcium phosphate powder (di calcium phosphate), and then through a sieve size 20 (850/0 mm) was granulated and dried at 40 ° C. The dried granules were sifting with sieve size 20 again. Finally purslane capsules were made granules containing dried extract of Portulaca oleracea extract as much as 500 mg per capsule at the Isfahan School Pharmacy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue

City
Isfahan

Postal code

Approval date
2013-10-28, 1392/08/06

Ethics committee reference number
392434

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
serum high sensitive-C Reactive Protein (hs-CRP) levels

Timepoint
In the first of intervention and end of 8th week

Method of measurement
mg/l-imonotorbidometry

2

Description
NON-HDL CHOL

Timepoint
In the first of intervention and end of 8th week

Method of measurement
Calculation method

3

Description
Waist circumference

Timepoint
In the first of intervention and end of 8th week

Method of measurement
meter, centimeter

4

Description
weight

Timepoint
In the first of intervention and end of 8th week

Method of measurement
scale, kilogram

5

Description
body mass index
Timepoint
In the first of intervention and end of 8th week
Method of measurement
kg/m2, Weight/Height square

6

Description
diastolic blood pressure
Timepoint
In the first of intervention and end of 8th week
Method of measurement
mmHg, Mercurial sphygmomanometer

7

Description
systolic blood pressure
Timepoint
In the first of intervention and end of 8th week
Method of measurement
mmHg, Mercurial sphygmomanometer

8

Description
fasting blood sugar
Timepoint
In the first of intervention and end of 8th week
Method of measurement
Enzymatic, mg/dL

9

Description
serum total cholesterol levels
Timepoint
In the first of intervention and end of 8th week
Method of measurement
Enzymatic, mg/dL

10

Description
serum High-Density Lipoprotein cholesterol (HDL-c) levels
Timepoint
In the first of intervention and end of 8th week
Method of measurement
Enzymatic, mg/dL

11

Description
serum Low-Density Lipoprotein cholesterol (LDL-c) levels
Timepoint
In the first of intervention and end of 8th week
Method of measurement
Calculation method

12

Description
fibrinogen
Timepoint
In the first of intervention and end of 8th week
Method of measurement
Clauss method

Secondary outcomes

empty

Intervention groups

1

Description
intervention group consume Purslane extract capsules. Two capsules 500 mg , one 30 minutes before breakfast and another 30 minutes before dinner.
Category
Treatment - Drugs

2

Description
control group consume placebo capsule for 2 months. 1 capsule 30 minutes before breakfast and 1 capsule 30 minutes before dinner. Placebo was made of calcium phosphate
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Oil Company hospital
Full name of responsible person
Mr Mokhtari
Street address
Isfahan Oil Company hospital- Artesh square- Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Isfahan University of Medical Science
Full name of responsible person
Peyman Adibi
Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue
City

Isfahan

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research,Isfahan University of Medical Science

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, School of Nutrition- School Nutrition Research Center

Full name of responsible person

Miss Samadanian

Street address

School Nutrition Research Center, School Of Nutrition and Food Sciences, Isfahan University Of Medical Sciences, Hezar Jerib Street, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, School of Nutrition- School Nutrition Research Center

Proportion provided by this source

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

Isfahan University of Medical Sciences

Full name of responsible person

Marjan Badakhanian

Position

MSc Student Of Nutrition

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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