

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences and 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 ($WC \geq 102$ 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>130mmhg 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 Samadani
Street address
School Nutrition Research Center, School Of Nutrition and Food Sciences, Isfahan University Of Medical Sciences, Hezar Jerib Street, Isfahan
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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

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Person responsible for updating data

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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