

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial of a period of resistance training with consumption of Portulaca oleracea supplement (applied to three groups including only exercise, only supplement and exercise-supplement and their comparison with the control group) on bone factors osteoprotegerin and nuclear factor kappa B in women with diabetes type II

Protocol summary

Summary

The aim of this single-blind (supplement and exercise-supplement groups blinding), clinical trial phase II was determining the effects of Purslane seed (Portulaca oleracea. L) with resistance training on Osteoprotegerin and nuclear factor kappa B (respectively OPG and NFκB) in women with diabetes type 2 was determined. The study population were included all women with diabetes type II in Sari city. 28 members of this community with a mean age of 52 years were divided into 4 groups with blocked randomization method. Inclusion criteria included diabetes type 2 and lack of exercise and exclusion criteria included health and drug therapy. The study period was eight weeks. Group A (7.5 g Purslane seed per day), group B (60 minutes resistance training, 3 days in a week), group C (did exercise as group B and used Purslane seed similar to group C) and group D (control). Amount of weight, OPG and NFκB factors were measured before and after eight weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051717249N4**
Registration date: **2015-06-03, 1394/03/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-03, 1394/03/13

Registrant information

Name

Farzanegi Parvin

Name of organization / entity

Islamic Azad University, Sari Branch

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University, Sari branch

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of a period of resistance training with consumption of Portulaca oleracea supplement (applied to three groups including only exercise, only supplement and exercise-supplement and their comparison with the control group) on bone factors osteoprotegerin and nuclear factor kappa B in women with diabetes type II

Public title

Effects of exercise and consumption of Purslane seeds on osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Not participating in regular physical activity during the last 6 months, Type 2 diabetic patients over 44 years. Exclusion criteria: History of cardiovascular disease, Smoking, Drug therapy (any drugs except Metformin) and if participant is healthy.

Age

From **44 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

None of the 2 groups, supplement and exercise-supplement were aware of the contents of capsules (single-blind)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University Sari Branch

Street address

7th km of Sea Road, Sari, Mazandaran, Iran

City

Sari

Postal code

Approval date

2015-05-11, 1394/02/21

Ethics committee reference number

Code: 1394-14, Number: 5-3273, Date: May 11, 2015.

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

Primary outcomes

1

Description

Osteoprotegerin

Timepoint

Before and 8 weeks after intervention

Method of measurement

ELISA method

2

Description

Nuclear factor kappa B

Timepoint

Before and 8 weeks after intervention

Method of measurement

ELISA method

Secondary outcomes

1

Description

Body weight

Timepoint

Before and 8 weeks after intervention

Method of measurement

Scale

Intervention groups

1

Description

Exercise group did resistance exercise with 40 to 50 percent One-repetition maximum by rubber band for 8 weeks, 3 sessions per week and 60 minutes per session

Category

Other

2

Description

Supplement group were consumed daily 7.5 g Purslane seed powder (2.5 g with lunch mile and 5 g with diner mile) mixed with yogurt for 8 weeks.

Category

Other

3

Description

Exercise- supplement group were consumed daily 7.5 g Purslane seed powder (2.5 g with lunch mile and 5 g with diner mile) mixed with yogurt for 8 weeks and also, did resistance exercise with 40 to 50 percent One-repetition maximum by rubber band for 8 weeks, 3 sessions per week and 60 minutes per session.

Category

Other

4

Description

The control group did not participate in any stages of study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarv club

Full name of responsible person

Roja Daliri

Street address

Qaran street, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University, Sari branch

Full name of responsible person

Dr. Mohammad Farsi

Street address

7th km of Sea Road, Sari, Mazandaran, Iran

City

Sari

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, Islamic Azad University, Sari branch

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

Islamic Azad University, Sari Branch

Full name of responsible person

Parvin Farzanegi

Position

PhD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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