

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of 6 Weeks of Low-Repetition and Light-Load Power Training on Serum Levels of b-ALP and CTX in Postmenopausal Women

Protocol summary

Study aim

Present study aims to survey effects of 6 weeks of low-repetition and light-load power training on serum Osteocalcin, Paratormone, Sclerostin, Bone Alkaline Phosphatase and C-terminal telopeptides of type I collagen in postmenopausal women.

Design

Clinical trial with control group, randomized, not blinded on 24 postmenopausal women. The table of random numbers will be used.

Settings and conduct

During menopause, reduced ovarian activity is associated with a drop in the level of hormones and its complications such as cardiovascular disease and osteoporosis. Present study are conducted in Zahedan city. 24 healthy and sedentary postmenopausal women will participate in this semi experimental study. They will be selected on purpose and will be randomly divided into two equal groups; experimental and control. Experimental group will perform 6 weeks low-repetition and light-load power training while control group wouldn't perform any activities.

Participants/Inclusion and exclusion criteria

Inclusion criteria were having no exercise background and no regular sport activity in past one year, at least two years should be passed from their menopause time, having no special problems such as cardiovascular, metabolic, kidney, orthopedic diseases and no smoking. The exclusion criteria include applying any medication, food supplements and diet therapy.

Intervention groups

The Training group which perform Low-Repetition and Light-Load Power Training and Control group don't participate in any physical exercises in intervention period.

Main outcome variables

Measurements of serum levels of Osteocalcin, Paratormone, Sclerostin, Bone Alkaline Phosphatase and C-terminal telopeptides of type I collagen.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043935N1**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Shila Nayebifar

Name of organization / entity

The University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2019-10-23, 1398/08/01

Trial completion date

2020-01-21, 1398/11/01

Scientific title

Effect of 6 Weeks of Low-Repetition and Light-Load Power Training on Serum Levels of b-ALP and CTX in Postmenopausal Women

Public title

Effect of Low-Repetition and Light-Load Power Training on Post menopausal Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having no exercise background At least two years should be passed from their menopause time. Not having any special problems such as cardiovascular, metabolic, kidney, orthopedic diseases. No smoking.

Exclusion criteria:

The exclusion criteria include applying any medication and food supplements, diet therapy. Being in amenorrhea state

Age

From **55 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization, Randomization unit: individually, Randomization tool: Table of Random Numbers, How to make Randomization sequence: From the top to the end of list, Allocation Concealment: A third person allocate numbers to the participants then using table of Random Numbers another person select the numbers with closed eyes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sistan and Baluchestan University

Street address

Daneshgah Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816976153

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

Code number: IR.USB.REC.1398.002

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Osteoporosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of Osteocalcin.

Timepoint

At the beginning of program (before starting intervention) and at the end of program (48 hours after last training session).

Method of measurement

Measurement of serum Osteocalcin will be assessed using a kit (Zell Bio, Germany) with a sensitivity of 0.026 ng/ml.

2

Description

Serum levels of Paratormone.

Timepoint

At the beginning of program (before starting intervention) and at the end of program (48 hours after last training session).

Method of measurement

Paratormon will be assessed using a kit (Zell Bio, Germany) with a sensitivity of 1.56 ng/ml.

3

Description

Serum levels of Sclerostin.

Timepoint

At the beginning of program (before starting

intervention) and at the end of program (48 hours after last training session).

Method of measurement

Sclerostin will be assessed using Hangzhou Stabiopharm kit (China), with a sensitivity of 0.26 ng/ml and ELISA method.

4

Description

Serum levels of Bone Alkaline Phosphatase.

Timepoint

At the beginning of program (before starting intervention) and at the end of program (48 hours after last training session).

Method of measurement

Bone Alkaline Phosphatase will be assessed using Hangzhou Stabiopharm kit (China), with a sensitivity of 0.52 pmol/l and ELISA method.

5

Description

Serum levels of C-terminal telopeptides of type I collagen.

Timepoint

At the beginning of program (before starting intervention) and at the end of program (48 hours after last training session).

Method of measurement

C-terminal telopeptides of type I collagen will be assessed using Hangzhou Stabiopharm kit (China), with a sensitivity of 0.01ng/ml and ELISA method.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Power trainings will be performed for 6 weeks, 5 sessions per week, 8 sets, 3 repetitions and 15 seconds rest between sets, including 5 activities (Scot, forward lunge, side lunge, cuff rise and toe rise) and to produce power in mentioned activities, the concentric phase should be done so fast in correct body straight posture. After 10 minutes of warm up the training starts and finished after 10 minutes of cool down.

Category

Prevention

2

Description

Control group: No intervention has received.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Shila Nayebifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of Sistan and Baluchestan

Full name of responsible person

Research minister

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Grant name

Grant code / Reference number

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

No

Title of funding source

University of Sistan and Baluchestan

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

shila_nayebifar@ped.usb.ac.ir

Contact

Name of organization / entity

The University of Sistan and Baluchestan

Full name of responsible person

Shila Nayebifar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available