

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effects of spinal stabilization exercise and Vitamin D intake on the levels of tumor necrosis factor- α and interleukin-10 in women with Chronic Low Back Pain

Protocol summary

Study aim

Compare of the effects of spinal stabilization exercise and vitamin D intake on tumor necrosis factor- α and interleukin-10 levels in women with chronic Low back pain

Design

This quasi-experimental study was conducted using a pretest-posttest design with a control group in a single blind manner. The subjects were randomly divided into four groups of control, exercise, vitamin D and combination. The training and combination groups perform 8 weeks of spinal stabilization exercises. Vitamin D and combination groups will receive 50,000 units of Vitamin D per week for 8 weeks.

Settings and conduct

The statistical population includes adult female patients with chronic low back pain referred to Ghaemshahr physiotherapy centers. Back bone stabilization exercises consist of 3 sets of 8 stretching and isometric exercises with one minute rest between exercises, three sessions per week, performed for 8 weeks at the Ghaemshahr Cultural Physiotherapy Clinic. Subjects in the vitamin D and combination groups, vitamin D and exercise and control groups, will receive placebo in a single blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being non-athlete, having low back pain for more than three months, having a moderate pre-test VAS score
Exclusion criteria: Smoking, using specific medications, becoming pregnant

Intervention groups

Intervention group 1: This group will do 3 sessions of spinal stabilization exercises for 8 weeks and will take placebo weekly. Intervention group 2: receive 50,000 IU of vitamin D per week. Intervention group 3: This group will receive 50,000 IU vitamin D with spinal stabilization exercises. Control group: Only placebo will be taken

weekly.

Main outcome variables

25- hydroxy vitamin D; Tumor necrosis factor- α ; interleukin-10; C Reactive protein; Pain; Functional Disability; Sleep quality; quality of life; lipid profile; liver enzymes, renal enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044650N1**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **retrospective**

Last update: **2020-03-02, 1398/12/12**

Update count: **0**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Masoumeh Habibian

Name of organization / entity

Qaemshahr Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 11 4224 1041

Email address

habibian.masoumeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-30, 1398/10/09

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of spinal stabilization exercise and Vitamin D intake on the levels of tumor necrosis factor- α and interleukin-10 in women with Chronic Low Back Pain

Public title

The Effects of spinal stabilization and Vitamin D on the tumor necrosis factor- α and interleukin-10 in women with Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having chronic low back pain for more than three months Pain score (based on visual analogue scale) moderate Not having regular exercise for the past six months

Exclusion criteria:

Use of specific drugs smoking Pregnancy

AgeFrom **30 years** old to **50 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **48****Randomization (investigator's opinion)**

Randomized

Randomization description

The subjects will be divided into four groups of control, exercise, vitamin D and combination (exercise + vitamin D) using simple randomization table. First a number is assigned to each person. Then, using the random number table of each selected number, it is assigned to one of the groups at random and will continue until the number of individuals in each group is completed. Therefore, the researcher will have no option to change or predict the status of individuals. Random concealment will be done by a third person who does not participate in other stages of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, evaluators, and analysts will be blind. The researcher will administer vitamin D capsules (50,000 units) to vitamin D and combination (vitamin D + exercise) individuals as well as placebo to control and exercise groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol branch, Islamic Azad University

Street address

Department of physical education, Qaemshahr branch, Islamic Azad University, Qaemshahr, Iran

City

Qaemshahr

Province

Mazandaran

Postal code

476516196

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.IAU.BABOL.REC.1398.086

Health conditions studied**1****Description of health condition studied**

chronic low back pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**Tumor necrosis factor- α **Timepoint**

Prior and after interventions

Method of measurement

Using the ELISA method

2**Description**

Interleukin-10

Timepoint

Prior and after interventions

Method of measurement

Using the ELISA method

3

Description

C reactive protein

Timepoint

Prior and after interventions

Method of measurement

Using the ELISA method

4

Description

25- hydroxy vitamin D

Timepoint

Prior and after interventions

Method of measurement

Using the ELISA method

5

Description

pain level

Timepoint

Prior and after interventions

Method of measurement

Visual Analogue Scale

6

Description

Severity of disability

Timepoint

Prior and after interventions

Method of measurement

the oswestry disability Questionnaire

7

Description

sleep quality

Timepoint

Prior and after interventions

Method of measurement

Petersburg Sleep Questionnaire

8

Description

Quality of Life

Timepoint

Prior and after interventions

Method of measurement

SF-36 Quality of Life Questionnaire

Secondary outcomes

1

Description

Aspartate aminotransferase

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

2

Description

Alkaline phosphatase

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

3

Description

Alanine aminotransferase

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

4

Description

urea

Timepoint

Before and after interventions

Method of measurement

Urease method

5

Description

uric acid

Timepoint

Before and after interventions

Method of measurement

Automatic colorimetric method

6

Description

creatinine

Timepoint

Before and after interventions

Method of measurement

Jaffe methods

7

Description

triglyceride

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

8

Description

total cholesterol

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

9

Description

low-density lipoprotein cholesterol (LDL-C)

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

10

Description

high-density lipoprotein cholesterol (HDL-C)

Timepoint

Before and after interventions

Method of measurement

Enzymatic method

Intervention groups

1

Description

Intervention group 1: Exercise group will perform 8 weeks of spinal stabilization exercises consisting of 3 sets of 8 stretching and isometric exercises with one minute rest between exercises, three sessions per week. Each exercise session starts from 3 seconds in the first week to 18 seconds in the fifth week, continuing through the eighth week (with a gradual increase of 3 seconds per week). Also, they will also take a placebo capsule weekly.

Category

Treatment - Other

2

Description

Intervention group II: Vitamin D group, who take 50,000 IU of vitamin D capsules once a week for 8 weeks in a single blind manner

Category

Treatment - Other

3

Description

Intervention group 3: Subjects in this group will have 8 weeks of spinal stabilization exercises similar to the exercise group and will consume 50,000 IU of vitamin D capsules once a week in a single blind manner.

Category

Treatment - Other

4

Description

Control group: There is no intervention in the control group and they are given placebo in a single blind manner.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian Physiotherapy Center

Full name of responsible person

Fazeleh Akbari

Street address

Farhang Street, Farhangian Physical Therapy Center, Qaemshahr, Iran.

City

Qaemshahr

Province

Mazandaran

Postal code

4765933187

Phone

+98 11 4220 2898

Email

habibian_m@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Qaemshahr Branch

Full name of responsible person

Dr Pyman Valipour

Street address

7 kilometers from Allameh Tabari Street, Islamic Azad University of Ghaemshahr Branch, Ghaemshahr, Iran.

City

Ghaemshahr

Province

Mazandaran

Postal code

4765161964

Phone

+98 11 4224 1041

Email

habibian_m@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Qaemshahr Branch

Proportion provided by this source

100

Public or private sector

Private

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

Contact

Name of organization / entity

Qaemshahr branch, Islamic Azad University

Full name of responsible person

Masoumeh Habibian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

7 kilometers from Allameh Tabari Street, Islamic Azad University of Ghaemshahr Branch, Ghaemshahr, Iran.

City

Qaemshahr

Province

Mazandaran

Postal code

4765161964

Phone

+98 11 4224 1041

Email

habibian_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qaemshahr branch, Islamic Azad University

Full name of responsible person

masoumeh habibian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

7km Allameh Tabarasi street, Qaemshahr Branch, Islamic Azad University, Qaemshahr

City

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Province

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Postal code

4765161964

Phone

+98 11 4224 1041

Email

habibian_m@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qaemshahr branch, Islamic Azad University

Full name of responsible person

Masoumeh habibian

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Phone

+98 11 4224 1041

Email

habibian_m@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

No - There is not a plan to make this available