Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Qaemshahar Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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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
Age
From **30 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target 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
Qeamshahr
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 Akbarniya
Street address
Farhang Street, Farhangian Physical Therapy Center, Qaemshahr, Iran.
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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.
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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

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Person responsible for updating data

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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