

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The Effects of spinal stabilization exercise and Vitamin D intake on the levels of tumor necrosis factor- $\alpha$ 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- $\alpha$  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- $\alpha$ ; 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- $\alpha$  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- $\alpha$  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**

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- $\alpha$

**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

4765161964

## Person responsible for general inquiries

### Phone

+98 11 4224 1041

### Email

habibian\_m@yahoo.com

### 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.

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#### Province

Mazandaran

#### Postal code

4765161964

#### Phone

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#### 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

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiology

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#### City

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#### 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

Physiology

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#### City

Qaemshahr

#### Province

Mazandaran

#### Postal code

## 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