

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the changes of Tumor necrosis factor- α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Protocol summary

Study aim

Investigating the changes of Tumor necrosis factor- α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Design

The present quasi-experimental study was performed using a pretest-posttest design with control group in a single blind manner. Subjects were randomly divided into four groups: control, Pilates exercise, vitamin D and combination. Pilates and combination training groups perform 8 weeks of Pilates training. Vitamin D and exercise+vitamin D groups will receive 50,000 IU of Vitamin D per week for 8 weeks

Settings and conduct

The statistical population includes sedentary adult men with overweight (body mass index between 25 and 29 kg / m²), aged 45-55 years, referred to Ghaemshahr sports clubs. Pilates exercises are performed at 50-70% of heart rate reserve and three sessions per week for 8 weeks at the Paya Sports Club in Ghaemshahr. 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 a non-athlete, being overweight
Exclusion criteria: smoking, use of special drugs, use of any supplements

Intervention groups

Intervention group 1: This group will do 3 sessions of Pilates training for 3 weeks and take placebo weekly.
Intervention group 2: receive 50,000 IU of vitamin D weekly.
Intervention group 3: In addition to Pilates exercises, they receive 50,000 IU of vitamin D. Control group: will only take placebo weekly.

Main outcome variables

25-Hydroxy vitamin D; tumor necrosis factor-alpha; interleukin 10; C reactive protein ; glucose, insulin,

insulin resistance, thyroid-stimulating hormone, lipid profile; liver enzymes; renal enzymes, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044650N2**

Registration date: **2020-03-18, 1398/12/28**

Registration timing: **retrospective**

Last update: **2020-03-18, 1398/12/28**

Update count: **0**

Registration date

2020-03-18, 1398/12/28

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

2019-12-31, 1398/10/10

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

Investigating the changes of Tumor necrosis factor- α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Public title

Effect of 8 weeks of Pilates exercise and vitamin D on Tumor necrosis factor- α and interleukin-10 levels in overweight men

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being overweight Not having regular exercise for the past six months Ability to perform exercise training Not having cardiovascular disease Not having hypertension

Exclusion criteria:

Use of specific drugs Use of supplement smoking

Age

From **40 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be divided into four groups of control, exercise, vitamin D and 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 and analysts will be blind. The researcher will administer vitamin D capsules (50,000 units) to vitamin D and exercise + vitamin D 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.1398.088

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

Obesity and overweight

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Tumor necrosis factor- α

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

2**Description**

25- hydroxy vitamin D

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

3**Description**

Interleukin-10

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

4

Description

Thyroid Stimulating Hormone

Timepoint

Before and after interventions

Method of measurement

immunochemiluminescence assay

5

Description

C-Reactive Protein

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

6

Description

insulin

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

7

Description

insulin resistance

Timepoint

Before and after interventions

Method of measurement

Using the homeostasis model(HOMA-IR)

Secondary outcomes

1

Description

Glucose

Timepoint

Prior and after interventions

Method of measurement

Glucose oxidase assay

2

Description

urea

Timepoint

Prior and after interventions

Method of measurement

Urease method

3

Description

uric acid

Timepoint

Prior and after interventions

Method of measurement

Automatic colorimetric method

4

Description

creatinine

Timepoint

Prior and after interventions

Method of measurement

Jaffe methods

5

Description

Triglyceride

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

6

Description

low-density lipoprotein cholesterol (LDL-C)

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

7

Description

high-density lipoprotein cholesterol (HDL-C)

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

8

Description

total cholesterol

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

9

Description

Aspartate aminotransferase

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

10

Description

Alkaline phosphatase

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

11**Description**

Alanine aminotransferase

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

Intervention groups**1****Description**

Intervention group 1: Exercise group will perform 8 weeks of Pilates exercises with 50-55% of heart rate reserve, one set and 10 repetitions in the first week and 65-70% reserve heart rate, 4 sets with 12 repetitions in eighth week (with increase A gradual 5% vigorous exercise, one set and 2 reps every two weeks). They will also take a placebo capsule containing oral paraffin weekly in a single blind manner

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 Pilates 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

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Paya Sports Club

Full name of responsible person

Fatemeh Eslami Vasmaleii

Street address

Babol Street, Paya Sports Club, Qaemshahr, Iran

City

Ghaemshahr

Province

Mazandaran

Postal code

4765933187

Phone

+98 11 4227 3833

Email

fatemeheslami0123@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qaemshahr branch, Islamic Azad University

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 4215 5221

Email

habibian_m@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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**

Other

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

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
Physiology

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

City
Qaemshahr

Province
Mazandaran

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

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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

City
Qaemshahr

Province
Mazandaran

Postal code
4765161964

Phone
+98 11 4224 1041

Email
habibian_m@yahoo.com

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