# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## Evaluating the effect of Cholecalciferol supplementation on inflammatory markers and muscle damage indices in soccer players after a simulated soccer match

## Protocol summary

**Summary**

The aim of study is to determine whether consumption of 50000 IU cholecalciferol supplement for eight weeks, will reduce the inflammation markers and muscle damage indices after a simulated soccer match in soccer players who have serum 25(oh)D3 concentration below 40 ng/ml. using a double-blind placebo-controlled design, 22 trained male soccer players , age group 18 to 30 years old, will inter the trial. after eight weeks supplementation with Cholecalciferol or a placebo, a validated simulated soccer match (Loughborough Intermittent Shuttle test) will be completed. during the trial, players who consume certain drugs or supplements, will be excluded. before the match and immediately after that and 2 and 24 hours after the match, blood samples were taken from the athletes for measuring the vitamin D, CPK (creatine phosphokinase), LDH (lactate dehydrogenase), IL-6 (Interleukin-6) and hs-CRP (high sensitive- C reactive protein) concentrations. the results will be compared between the groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017042613678N27**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-06-26, 1396/04/05

**Registrant information**

**Name**

Saeed Ghavamzadeh

**Name of organization / entity**

Urmia University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Urmia University of Medical Sciences

**Expected recruitment start date**

2016-08-21, 1395/05/31

**Expected recruitment end date**

2017-01-19, 1395/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effect of Cholecalciferol supplementation on inflammatory markers and muscle damage indices in soccer players after a simulated soccer match

**Public title**

Effect of vitamin D on inflammation and muscle damage in athletes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria: soccer players who want to collaboration; players who regularly and consistently participate in soccer practices and matches(at least 4

month passed from starting this sport); age group between 18 to 30 years old; healthy players without any injury, cardio-metabolic disease, orthopedic and inflammatory disease; players without any acute liver disease, biliary, kidney and digestive disease; players with no history of kidney stone and hyperparathyroidism and osteomalasia or osteoporosis and sarcoidosis; lack of vitamin D supplementation at least for 8 weeks before the study beginning; lack of using drugs which can affect vitamin D level and its metabolism and function such as steroid and anti-epileptic drugs; lack of using certain drugs such as acetaminophen and anti-inflammatory drugs and b blockers and statins; lack of using exogenous hormones; lack of using amphotericin B,ampicilin, anticoagulant drugs, aspirin, clofibrate, cocaine, lithium, furosemide, morphine and some of anesthetic drugs; lack of using epinephrine and sodium bicarbonate; lack of using orlistate and cholestyramine and other cholesterol reducing drugs; people by BMI group 18.5 to 30; lack of smoking and alcohol consumption; people with 25(oh)D serum concentration less than 40 ng/mL. exclusion criteria: lack of collaboration for continuing the study; using certain drugs during the study; using foods rich in vitamin D specially canned fish, cod fish oil, Salmon and vit D fortified foods; using less than 80 % of supplements; traveling to place with sunny weather during the study; injury or disease occurrence during the study.

**Age**
From **18 years** old to **30 years** old

**Gender**
Male

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **22**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
Randomization method was Balanced block.

## Secondary Ids

### 1

**Registry name**
-

**Secondary trial Id**
-

**Registration date**
empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Urmia University of Medical Sciences

**Street address**
urmia, staff of urmia university of medical sciences

**City**
urmia

**Postal code**
-

**Approval date**
2016-10-26, 1395/08/05

**Ethics committee reference number**
Ir.umsu.rec.1395.303

## Health conditions studied

### 1

**Description of health condition studied**
inflammation

**ICD-10 code**
-

**ICD-10 code description**
-

### 2

**Description of health condition studied**
muscle damage

**ICD-10 code**
-

**ICD-10 code description**
-

## Primary outcomes

### 1

**Description**
Interleukin 6

**Timepoint**
at the end of the trial: before the simulated test, immediately after the test, 2 and 24 hours after the test

**Method of measurement**
lab test

### 2

**Description**
CRP

**Timepoint**
at the end of the trial: before the simulated test, immediately after the test, 2 and 24 hours after the test

**Method of measurement**
lab test

### 3

**Description**
lactate dehydrogenase
**Timepoint**
at the end of the trial: before the simulated test, immediately after the test, 2 and 24 hours after the test
**Method of measurement**
lab test

### 4

**Description**
creatine phosphate kinase
**Timepoint**
at the end of the trial: before the simulated test, immediately after the test, 2 and 24 hours after the test
**Method of measurement**
lab test

### 5

**Description**
serum 25-oh vitamin D3 level
**Timepoint**
before and after the trial: immidiately before the soccer simulated test
**Method of measurement**
lab test

### 6

**Description**
Body composition
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Body composition analyzer (BIA)

## Secondary outcomes

### 1

**Description**
Rating of Perceived Exertion
**Timepoint**
immidiately after each partof the simulated test
**Method of measurement**
questionnaire

## Intervention groups

### 1

**Description**
Experimental group will receive supplement for 8 weeks (each week they should eat one 50000 IU cholecalciferol pearl). After 8 weeks, players will participate in a simulated soccer match at the test day. The protocol of the simulated soccer match is according to Loughbrough intermittent shuttle run test. The test comprised two parts, Part A and Part B. Part A was of a fixed duration and consisted of five 15 min exercise periods separated by 3 min of recovery. The exercise periods consisted of a set pattern of intermittent high-intensity running, and were designed to be similar to the activity pattern typically recorded for soccer match play. The pattern of exercise for Part A was as follows: 3 ´ 20 m at walking pace; 1 ´ 20 m at maximal running speed; 4 s recovery; 3 ´ 20 m at a running speed corresponding to 55% of individual VO2max; 3 ´ 20 m at a running speed corresponding to 95% of individual VO2max This pattern of exercise was repeated for each 15 min block followed by a rest period of 3 min. Altogether, five15 min exercise blocks were completed, separated by 3 min of recovery, before the start of Part B. Part B was an open-ended period of intermittent shuttle running, designed to exhaust the participants within approximately 15 min. The participants were required to run at speeds corresponding to 55% and 95% of predicted VO2max , the speed alternating every 20 m. This pattern of exercise was repeated continuously until the participants were unable to maintain the required speed for two consecutive shuttles at the higher of the two exercise intensities.
**Category**
Treatment - Other

### 2

**Description**
Control group will receive placebo for 8 weeks (each week they should eat one oral paraffin pearl). After 8 weeks, players will participate in a simulated soccer match at the test day. The protocol of the simulated soccer match is according to Loughbrough intermittent shuttle run test. The test comprised two parts, Part A and Part B. Part A was of a fixed duration and consisted of five 15 min exercise periods separated by 3 min of recovery. The exercise periods consisted of a set pattern of intermittent high-intensity running, and were designed to be similar to the activity pattern typically recorded for soccer match play. The pattern of exercise for Part A was as follows: 3 ´ 20 m at walking pace; 1 ´ 20 m at maximal running speed; 4 s recovery; 3 ´ 20 m at a running speed corresponding to 55% of individual VO2max; 3 ´ 20 m at a running speed corresponding to 95% of individual VO2max This pattern of exercise was repeated for each 15 min block followed by a rest period of 3 min. Altogether, five15 min exercise blocks were completed, separated by 3 min of recovery, before the start of Part B. Part B was an open-ended period of intermittent shuttle running, designed to exhaust the participants within approximately 15 min. The participants were required to run at speeds corresponding to 55% and 95% of predicted VO2max , the speed alternating every 20 m. This pattern of exercise was repeated continuously until the participants were unable to maintain the required speed for two consecutive shuttles at the higher of the two exercise intensities.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Urmia commission of soccer

**Full name of responsible person**
Narges Parsaie

**Street address**
Takhti stadium, Motahhari street, Urmia

**City**
Urmia

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice Chancellor for research of Urmia university of medical sciences

**Full name of responsible person**
Dr Iraj Mohebbi

**Street address**
Urmia University of Medical Sciences staffs department, Orjhans Street, Resalat Blvd, Urmia, Iran

**City**
Urmia

**Grant name**
-

**Grant code / Reference number**
-

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

**Title of funding source**
Vice Chancellor for research of Urmia university of medical sciences

**Proportion provided by this source**
100

**Public or private sector**
*empty*

**Domestic or foreign origin**
*empty*

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

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**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*