Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Contact

Name of organization / entity
Urmia university of medical sciences

Full name of responsible person
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Position
Ph.D/Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Web page address
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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