Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of high protein supplementation on inflammatory indicators and muscle damage on basketball athletes in Kermanshah

Protocol summary

Study aim
Effect of high protein supplementation on inflammatory indices and muscle damage on basketball athletes

Design
This randomized double-blind controlled clinical trial with parallel groups will be conducted on 44 healthy young men who will be randomly categorized into control and intervention groups.

Settings and conduct
This study will be conducted during 8 weeks on 44 basketball men who are members of clubs approved by the basketball board of Kermanshah province. After explaining the purpose of the study and obtaining informed consent, the participants will be evaluated in term of anthropometric indices, nutritional status, inflammatory indices and painful muscle index. For evaluation of blood inflammatory indices, 10 cc fasting blood samples will be obtained. Then the participants will be classified into control and intervention groups in which the researcher and the participants will not be aware of the groups allocation. The control group will receive 25 grams daily of Whey protein supplement and the control group will receive the same amount of placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants should be male; New member of basketball team; Age range between 20-30 year; Body mass index (BMI) between 20-25 kg/m2; Voluntary participation. Exclusion criteria: Having systemic diseases or having a history of trauma; Under the diet and special diet plan, up to 6 months before the study; Use of any dietary supplement and exercise up to 6 months before the study;

Intervention groups
The first group will receive 25 grams of Whey protein supplement (3 doses of 8.3 g at 10 A.M, 1 P.M and 4 P.M) daily and the second group will receive placebo (25 g of starch at the same time and the same amount).

Main outcome variables
Blood inflammatory index; Painful muscle index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181111041611N1**
Registration date: **2019-03-09, 1397/12/18**
Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**
Update count: **0**

Registration date
2019-03-09, 1397/12/18

Registrant information

Name
Mehnoosh Samadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3710 2009

Email address
mehnoosh_samadi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-21, 1397/09/30

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of high protein supplementation on inflammatory indicators and muscle damage on basketball athletes in Kermanshah

Public title
Effect of high protein supplementation on inflammatory indicators and muscle damage on basketball athletes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Participants should be male New member of basketball team Age range between 20-30 year Body mass index (BMI) range between 20-25 kg/m2 Voluntary participation
Exclusion criteria:
Having systemic diseases or having a history of trauma Under the diet and special diet plan, up to 6 months before the study Use of any dietary supplement and exercise up to 6 months before the study

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the draw method: The names of the participants will be written on the separate papers and will be placed inside a container. Then the names of the participants will be withdrawn randomly and will be placed in the intervention or control groups. The first 20 names will be placed in the intervention group and the rest in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researchers and participants will not be aware of the allocation of groups, and the supplements appearance will be similar in both groups. The supplemented manufacturer will encoded the supplements before delivery.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.
City
Kermanshah
Province
Kermanshah
Postal code
6719851351

Approval date
2018-10-14, 1397/07/22

Ethics committee reference number
IR.KUMS.REC.1397.561

Health conditions studied

1

Description of health condition studied
Inflammatory indices

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Musculoskeletal Indicator

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Percentage of subjects with low inflammation index

Timepoint
Before the intervention and 8 weeks after starting to consume high protein supplement

Method of measurement
Measurement of inflammatory indices and painful muscular questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the intervention will be conducted

with 25 grams of Whey protein supplement (Karenpharma co, Canada, Representation in Iran) 90% (in 3 doses of 8.3 gr at 10 am, 1 noon and 4 am) daily.

Category

Prevention

2

Description

Control group: With 25 g of starch (placebo) (in 3 doses of 8.3 g at 10 am, 13 noon and 16 am), it will be done daily.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clubs approved by the basketball board of Kermanshah province

Full name of responsible person

Karam Ahmadian

Street address

Gomrek Street, Kermanshah, Iran

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6714897767

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shimamoradi21@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Building No. 2, Research Council Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, 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

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehnoosh Samadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Nutrition

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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
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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
Trail that began to fall ill on 11th of January 1397 should have a release plan when recording its study protocol.
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