

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

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

#### Protocol summary

Blood inflammatory index; Painful muscle index

#### 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/m<sup>2</sup>; 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

#### 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/m<sup>2</sup> 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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714897767

**Phone**

+98 83 3823 0218

**Email**

shimamoradi21@yahoo.com

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3837 6892

**Email**

fnajafi@kums.ac.ir

**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

**Street address**

School of Nutrition and Food Sciences, Above Farabi Hospital, Ilesar Square

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719851351

**Phone**

+98 83 3710 2009

**Email**

mehnoosh\_samadi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ghoush University of Medical Sciences

**Full name of responsible person**

Mohamad Hozoori

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Qom University of Medical Sciences, Shahid Lavasani Street

**City**  
Qom  
**Province**  
Ghoum  
**Postal code**  
3713649373  
**Phone**  
+98 25 3612 2028  
**Email**  
mhozoori@yahoo.com

**Province**  
Kermanshah  
**Postal code**  
67146-97767  
**Phone**  
+98 838358058  
**Email**  
moradi1991@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Mohamad Moradi  
**Position**  
student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
No. 5, Alley 143, Markazy  
**City**  
Kermanshah

## 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