

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The effect of 8 weeks of milk protein concentrate supplementation on the level of blood lactate ,creatine kinase ,lactate dehydrogenase ,c-reactive protein in CrossFit men

#### Protocol summary

##### Study aim

Determining the effect of 8 weeks of milk protein concentrate supplementation on blood lactate, creatine kinase, lactate dehydrogenase and C-reactive protein levels in CrossFit men.

##### Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 100 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

Both groups will do crossfit exercises for 8 weeks and 4 sessions every week. Both groups will take 40 grams of the prescribed supplement and placebo one hour before going to sleep every night for 8 weeks. Exercises will be done in the Crossfit gym in Qasr Shirin city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being at least 18 years old; Maximum 35 years; Having at least 6 months of training experience in CrossFit Exclusion criteria: no injuries, no smoking and alcohol consumption; Not taking medical drugs or any sports supplements

##### Intervention groups

Using the table of random numbers, the subjects were divided into two groups: supplement with exercise and placebo with exercise. The supplement group with training consumed milk protein concentrate and the placebo group consumed maltodextrin with training.

##### Main outcome variables

Blood lactate, lactate dehydrogenase, creatine kinase, reactive protein c

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231228060556N1**

Registration date: **2024-02-14, 1402/11/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

##### Registration date

2024-02-14, 1402/11/25

##### Registrant information

###### Name

Sajad Yavari

###### Name of organization / entity

The University of Razi

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 4242 5563

###### Email address

syavari698@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-10, 1402/10/20

##### Expected recruitment end date

2025-03-10, 1403/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of 8 weeks of milk protein concentrate supplementation on the level of blood lactate ,creatine kinase ,lactate dehydrogenase ,c-reactive protein in

CrossFit men

## Public title

Investigating the effect of milk protein concentrate supplementation on CrossFit athletes.

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age range from 20 to 35 years Having at least 6 months of CrossFit training experience

### Exclusion criteria:

Having an injury Taking any medical drugs or nutritional or sports supplements Using tobacco or alcohol or psychotropic drugs

## Age

From **20 years** old to **35 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Tables of Random numbers are prepared by computers that arrange numbers randomly.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this research work, a person outside the research work was requested to help us as a helper in determining the supplement and placebo group. Then he determined the desired groups using a table of random numbers.

## 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

No. 4, Farvardin 3 Ave., Perozzi Street

##### City

Qhaser-shirin

##### Province

Kermanshah

## Postal code

6781733931

## Approval date

2023-11-29, 1402/09/08

## Ethics committee reference number

IR.RAZI.REC.1402.089

## Health conditions studied

### 1

#### Description of health condition studied

The effect of milk protein concentrate on inflammatory factors in CrossFit athletes

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Blood lactate

#### Timepoint

Before starting and after the end of 8 weeks

#### Method of measurement

By Blood measurements

### 2

#### Description

Lactate dehydrogenase

#### Timepoint

Before starting and after the end of 8 weeks

#### Method of measurement

By Blood measurements

### 3

#### Description

Reactive Protein C

#### Timepoint

Before starting and after the end of 8 weeks

#### Method of measurement

By Blood measurements

### 4

#### Description

Creatine Kinase

#### Timepoint

Before starting and after the end of 8 weeks

#### Method of measurement

By Blood measurements

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: The intervention group consists of 12 CrossFit athletes who receive 40 grams of milk protein concentrate daily one hour before bed for 8 weeks and do CrossFit training 4 times a week.

### Category

Other

## 2

### Description

Control group: The control group consists of 12 CrossFit athletes who receive 40 grams of maltodextrin placebo one hour before bed for 8 weeks and do CrossFit training 4 times a week.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Persian experimenters

##### Full name of responsible person

Sajad Yavari

##### Street address

Parsian Laboratory, Corner of Sixth Alley, Mustafa Emami Blvd, Kermanshah city

##### City

Kermansha

##### Province

Kermanshah

##### Postal code

67146-35585

##### Phone

+98 83 3822 8075

##### Email

syavari698@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

razi university

##### Full name of responsible person

mostafa mostafae

##### Street address

kermanshah-razi-university

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714414971

##### Phone

+98 83 3428 3272

#### Email

mo.azizi@razi.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

razi university

#### 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

The University of Razi

##### Full name of responsible person

Sajad Yavari

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nutrition

##### Street address

No. 4, Farvardin 3 Alley., Perozzi Street

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## Person responsible for scientific inquiries

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Sajad Yavari

**Position**

student

**Latest degree**

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**Other areas of specialty/work**

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**Street address**

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**City**

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**Province**

**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