

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of probiotic supplement on immune system response in male Athlete

#### Protocol summary

##### Summary

Aim: The aim of this study is compare the effects of probiotic supplementation on the changes levels of lymphocytes(LY) and monocytes(MO), granulocytes (GR)and CRP, IgA serum of male athletes before and after exhaustive exercise. Methods: In a double-blind placebo-controlled study, 16 male volunteers aged between 19-25 years were assigned into two groups probiotic (n=8) and placebo (n=8). Inclusion Criteria were being healthy male , without history of CHD diseases. Also exclusion criteria including consumption of diary, affected to sport injury, abling to do sport test. Subjects consumed 2 capsules probiotic /day or 2 capsules placebo /day for 30 days. The fasting blood samples were collected at the beginning of the study and the end of 30 days before and after exhaustive exercise(Bruce test). Lymphocytes, monocytes, granulocytes, IgA and CRP in serum were analyzed.

#### General information

##### Acronym

Effect of probiotic supplement on immune system response in male Athlete

##### IRCT registration information

IRCT registration number: **IRCT2013122115883N1**  
Registration date: **2014-01-27, 1392/11/07**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-01-27, 1392/11/07

##### Registrant information

###### Name

Marzieh Aghaei

###### Name of organization / entity

Qom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3665 6917

###### Email address

dr.ambeigi@muq.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

None

###### Expected recruitment start date

2011-04-21, 1390/02/01

###### Expected recruitment end date

2011-05-22, 1390/03/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of probiotic supplement on immune system response in male Athlete

###### Public title

Effect of probiotic supplement on immune system response in male Athlete

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion Criteria: Being athletic; being healthy male ; without history of CHD diseases Exclusion Criteria: Consumption of diary; affected to sport injury; ability on donig sport test.

###### Age

From **19 years** old to **25 years** old

###### Gender

Male

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **16**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Alzahra University

##### Street address

Faculty of Sport, Deh Vanak, Tehran

##### City

Tehran

##### Postal code

##### Approval date

2011-05-16, 1390/02/26

##### Ethics committee reference number

486/12/90-3

## Health conditions studied

### 1

#### Description of health condition studied

Immunity system

#### ICD-10 code

D80.2

#### ICD-10 code description

Selective deficiency of immunoglobulin A [IgA]

## Primary outcomes

### 1

#### Description

Lymphosite

#### Timepoint

After one month

#### Method of measurement

CBC

## Secondary outcomes

### 1

#### Description

IGA

#### Timepoint

After one month

#### Method of measurement

CBC Test

## Intervention groups

### 1

#### Description

2 probiotic capsules per day for 30 days (60 capsules )  
with 2 million microorganism per each capsules

#### Category

Prevention

### 2

#### Description

60 placebo capsule contain carbohydrate for 30 days (2  
per day) assigned to control group.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Sport Science

##### Full name of responsible person

Marzieh Aghaei

##### Street address

Hazrate Masoumeh Hospital, Qom

##### City

Qom

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Marzieh Aghaei

##### Full name of responsible person

Marzieh Aghaei

##### Street address

Hazrate Masoumeh Hospital- Qom

##### City

Qom

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Marzieh Aghaei

**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**

Qom Univ Med Sci

**Full name of responsible person**

Marzieh Aghaei

**Position**

MSc

**Other areas of specialty/work****Street address**

Taghavi, 45 metri Modares

**City**

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

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**Full name of responsible person**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Marzieh Aghaei

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****Web page address****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*