

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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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 sizeTarget 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**

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Qom University of Medical Sciences

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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