Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 diseses. 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 diseses Exclusion Criteria: Consumption of diary; affected to sport injury; ablity 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 Commitee 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-د

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 milion 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
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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
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00
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