

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Probiotic yogurt effects on performance, respiratory and digestive system of endurance adolescent female swimmers

Protocol summary

Summary

The aim of this study is determination the effect of probiotic yogurt on performance and health status of young adult women endurance swimmers. In a randomized controlled trial 46 girl endurance swimmers aged 11 to 17 years who had taken part in the national 400 and 800 meter crawl swimming competitions of 2009 will be studied. Subjects will be randomly assigned to two groups, receiving daily for 8 weeks, either 400 ml probiotic yogurt (intervention) or ordinary yogurt (control). At the beginning and at the end of the study, the 400-m free swimming record will be determined and the Harvard Step test will be employed to measure VO2max.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122311849N1**

Registration date: **2013-01-19, 1391/10/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-19, 1391/10/30

Registrant information

Name

Nahid Salarkia

Name of organization / entity

National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Te

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7486

Email address

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Recruitment status

Recruitment complete

Funding source

International Branch, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2009-06-21, 1388/03/31

Expected recruitment end date

2009-08-22, 1388/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Probiotic yogurt effects on performance, respiratory and digestive system of endurance adolescent female swimmers

Public title

Probiotic yogurt effects on health status and performance of endurance adolescent female swimmer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :being healthy; having the 400 meter crawl swimming time less than 6 min. 20 Sec . Exclusion criteria: acute gastrointestinal symptoms ; intake antibiotics for two months before the study.

Age

From **11 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute

Street address

46, West Arghavan St., Farahzadi Blv. Shahrak-E-Qods. Tehran, POBOX 19395-4741, IRAN,

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

NA

Health conditions studied

1

Description of health condition studied

Performance and respiratory and digestive disease

ICD-10 code

J00,J02,J0

ICD-10 code description

common cold, Sore throat, Influenza, Gastro-oesophageal reflux disease

Primary outcomes

1

Description

VO2max

Timepoint

Harvard Step test will be employed to measure VO2max will be performed at the beginning and end of week eight

Method of measurement

Harvard Step test will be employed to measure VO2max.

The athlete step up and down off a 41cm high bench for 3 minutes at a rate 22 steps/minute. On finishing the test the number of heart beats will be counted for 15 seconds. The number of beats will be multiplied in 15 seconds by 4 to give the "step test pulse rate". This final value will be used to assess the athlete's VO2max in ml/kg/min.

Secondary outcomes

1

Description

stomachache, vomiting and diarrhea; respiratory infections such as: rhinitis, fever, sore throat, cough, chest ailing breath by sound, ear pain

Timepoint

at the beginning and end of week eight

Method of measurement

All subjects will be asked to record the digestive symptoms such as: stomachache, vomiting and diarrhea; respiratory infections such as: rhinitis, fever, sore throat, cough, chest ailing breath by sound, ear pain; the extent of exercise per meter; the intake of medicine and quantity of the consumed foodstuff product which had been recommended, on the provided questionnaires, daily. The subjects will be advised to refrain from other probiotic products which were outside the project plan

Intervention groups

1

Description

Intervention group : Receiving 400 ml yogurt Probiotic containing 4×10^{10} cfu/ml (Colony forming unit per millimeter) comprising of Lactobacillus Acidophilus SPP, Lactobacillus Delbrueckii Bulgaricus, Bifidobacterium Bifidum, and Streptococcus Salivarius Thermnophilus, (n=23) and group

Category

Prevention

2

Description

Control group: Receiving similar dose of ordinary yogurt

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

National Nutrition and Food Technology Research Institute

Full name of responsible person

Nahid Salarkia-Leili Ghadamli

Street address

46, West Arghavan St., Farahzadi Blv. Shahrak-E-

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

self financial

Full name of responsible person

Leili Ghadamli

Street address

International Branch, Shahid Beheshti University of
Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

self financial

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

self financial

Full name of responsible person

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Street address

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Medical Sciences, Tehran

City

Tehran

Grant name

Grant code / Reference number

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Proportion provided by this source

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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Medical Sciences, Tehran, Iran.

Full name of responsible person

Leili Ghadamli

Position

M.Sc in Nutrition Sciences

Other areas of specialty/work

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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