

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

n.salarkia@nnftri.ac.ir

##### 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  $4 \times 10^{10}$  cfu/ml (Colony forming unit per millimeter) comprising of Lactobacillus Acidophilus SPP, Lactobacillus Delbrueckii Bulgaricus, Bifidobacterium Bifidum, and Streptococcus Salivarius Thermophilus, (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-

Qods. Tehran, POBOX 19395-4741, IRAN,  
**City**  
Tehran

## 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**

Leili Ghadamli

**Street address**

International Branch, Shahid Beheshti University of  
Medical Sciences, Tehran

**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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

, International Branch, Shahid Beheshti University of  
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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## Person responsible for scientific inquiries

### Contact

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**Position**

Assistant Research

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**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*