

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

the effects of probiotic yogurt and regular one on balance of Tcells in obese and overweight persons : double blind randomized clinical trial

Protocol summary

Summary

This research is double blind study that we will examine the overweight and obese person with BMI between 25-35. We take 10 cc blood from participants. we have 3 groups : 25 persons that will eat probiotic yogurt with L.casei DN01 - lactobacillus acidophilus La5- Bifidobacter bb12. With weight reduction diet, 25 persons that will eat probiotic yogurt with L.casei DN01 - lactobacillus acidophilus La5- Bifidobacter bb12. Without weight reduction diet ,25 persons that will eat regular yogurt with weight reduction diet. The duration of intervention is 8 weeks. IL9-IL4-IL10-IL17-TGF B- IFN - TNF alpha - hsCRP -leptin will measure with ELIZA and real time PCR method. With BIA method we will measure the fat percent of the body of participants (after and before of study).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111082709N21**

Registration date: **2011-12-20, 1390/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-20, 1390/09/29

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2011-09-17, 1390/06/26

Expected recruitment end date

2012-02-18, 1390/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effects of probiotic yogurt and regular one on balance of Tcells in obese and overweight persons : double blind randomized clinical trial

Public title

effect of probiotics on function of immune system in obesity

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age of 20-50;BMI= 25-35;interesting in participation in research; without any metabolic disease , CHD, diabetes , without autoimmune disease , cancer; without infection disease in research ;without allergy for cow s milk; no smoking ; no alcoholism; without immune system suppressor drugs 6 mounts before research; no menstrual bleeding ;without any diet 2 mounts before research ;no consumption food supplementation during research exclusion criteria: metabolic disease , CHD, diabetes , autoimmune disease , cancer; infection disease in research ; allergy for cow s milk; smoking ;

alcoholism; immune system suppressor drugs 6 months before research; menstrual bleeding; diet 2 months before research; lactose deficiency; food supplementation during research; no interesting for participation

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Tehran University of Medical Science

Street address

Enghelab street - Tehran- Iran

City

Tehran

Postal code

0098

Approval date

2011-11-08, 1390/08/17

Ethics committee reference number

1701/130/90/ص

Health conditions studied

1

Description of health condition studied

overweight and obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

fat percent

Timepoint

after and before of intervention

Method of measurement

BIA method

2

Description

BMI

Timepoint

after and before of intervention

Method of measurement

formula

3

Description

IL4-IL9-IL10- IL17- TNF alpha - IFN gama- TGF beta

Timepoint

after and before of intervention

Method of measurement

ELIZA

4

Description

transcription factor of Foxp3 - TGF beta - TNF alpha - GATA3- t-bet -ROR gama IN PBMC

Timepoint

after and before of intervention

Method of measurement

real time- PCR

5

Description

Leptin

Timepoint

after and before of intervention

Method of measurement

ELIZA

6

Description

hsCRP

Timepoint

after and before of intervention

Method of measurement

ELIZA

Secondary outcomes

1

Description

waist circumference

Timepoint

after and before of intervention

Method of measurement

meter

Intervention groups**1****Description**

25 overweight and obese persons with weight reduction and consumption of probiotic yogurt with lactobacillus acidophilus La5 and lactobacillus casei DN001 and bifidobacter bb12

Category

Prevention

2**Description**

25 overweight and obese persons with weight reduction and consumption of regular yogurt with lactobacillus bulgaricus and Streptococcus thermophilus

Category

Placebo

3**Description**

25 overweight and obese persons without weight reduction and consumption of probiotic yogurt with lactobacillus acidophilus La5 and lactobacillus casei DN001 and bifidobacter bb12

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

The clinic of weight management , Azad university

Full name of responsible person

Zarrati

Street address

Iran zamin street , Sardare jangal street , Poonak square - Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran university of Medical Science

Full name of responsible person

Mardani

Street address

Central Building of Tehran university of medical

scienc , Boolvar Keshavarz , Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran university of Medical Science

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**

School of Public Health , Tehran University of Medical Science

Full name of responsible person

dr. farzad shidfar

Position

associate professor

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

Faculty of nutrition , School of Public Health, Alvand street

City

Tehran

Postal code**Phone**

+98 21 8877 9118

Fax**Email**

farzadshidfar@yahoo.com

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

School of Public Health, Tehran University of Medical Science

Full name of responsible person

dr. farzad shidfar

Position

PhD of nutrition

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

Faculty of Nutrition, School of Public Health, Alvand street

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

farzadshidfar@yahoo.com

Web page address

Person responsible for updating data

Contact

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