

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effects of probiotic yogurt consumption on some inflammatory biomarkers (hs-CRP,IL-6,TNF- α),glacated hemoglobine,lipid profile and gi symptoms in patients with type 2 diabetes

Protocol summary

Summary

The purpose of this study is to compare the effect of probiotic and conventional yogurt on some biochemical parameters in patients with type 2 diabetes. Forty- four patients with type 2 diabetes from both of sex and aged between 35-55 years old are assigned to two intervention and control groups. The subjects in the intervention group consum 300 g/d probiotic yogurt(contained Bifidobacterium animalis subsp. lactis (Bb12) and Lactobacillus acidophilus La5) and subjects in the control group consum 300g/d conventional yogurt for 8 weeks. Anthropometric indices, dietary intakes, serum levels of glucose, IL-6, TNF- α , hs-CRP, HbA1c, lipid profile and gi symptoms are evaluated at the beginning and end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021516588N1**

Registration date: **2014-03-04, 1392/12/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-04, 1392/12/13

Registrant information

Name

Fatemeh Mohammadi

Name of organization / entity

School of Paramedicine, Ahvaz Jondishapur University
Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jondishapur
University Of Medical Sciences

Expected recruitment start date

2012-01-05, 1390/10/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of probiotic yogurt consumption on some inflammatory biomarkers (hs-CRP,IL-6,TNF- α),glacated hemoglobine,lipid profile and gi symptoms in patients with type 2 diabetes

Public title

The effects of probiotic yoghurt on type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having type 2 diabetes, 35 to 55 years old, BMI \leq 30, LDL level more than 100 mg/dl. Exclusion criteria: cardiovascular disease,renal dysfunction,chronic inflammatory diseases; inflammatory bowel disease, thyroid disorders and lactose intolerance, treatment with insulin and taking corticosteroids, NSAIDS, immunosuppressives, cholesterol lowering drugs,

multivitamin-mineral , fiber and omega 3 supplements, smoking, pregnancy and lactation, having any weight loose or weight gain regimes, use of antibiotics

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City

Ahvaz

Postal code

Approval date

2012-01-07, 1390/10/17

Ethics committee reference number

ETH.363

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

Before and after 8 weeks

Method of measurement

Chromatography

2

Description

Fasting Blood Sugar

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

3

Description

Total Cholesterol

Timepoint

Before and after 8 weeks

Method of measurement

Spectrophotometry

4

Description

Triglyceride

Timepoint

Before and after 8 weeks

Method of measurement

Spectrophotometry

5

Description

HDL-c

Timepoint

Before and after 8 weeks

Method of measurement

Spectrophotometry

6

Description

LDL-c

Timepoint

Before and after 8 weeks

Method of measurement

Friedewald Formula

7

Description

hs-CRP

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

8

Description

TNF- α

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

9

Description

Interlukine-6

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

10

Description

Gi symptoms

Timepoint

Before and after 8 weeks

Method of measurement

Gi symptoms questionnaire

Secondary outcomes

1

Description

Dietary Factors

Timepoint

Before and after 8 weeks

Method of measurement

3-day 24h dietary recalls

2

Description

Hip circumference

Timepoint

Before and after 8 weeks

Method of measurement

Meter

3

Description

Body weight

Timepoint

Before and after 8 weeks

Method of measurement

Digital scale

4

Description

Waist circumference

Timepoint

Before and after 8 weeks

Method of measurement

Meter

Intervention groups

1

Description

The subjects in the intervention group consume 300 g/d probiotic yogurt containing 10⁶ colony of both Lactobacillus acidophilus and Bifidobacterium lactis bacteria

Category

Treatment - Drugs

2

Description

Subjects in the control group consume 300g/d conventional yogurt.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital Endocrine Clinic

Full name of responsible person

Fatemeh Mohammadi

Street address

Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jondishapur University Of Medical Sciences

Full name of responsible person

Dr Majid Karandish

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Ahvaz Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

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Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jondishapur University Of Medical Sciences

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

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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