

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of synbiotic yogurt consumption on liver echogenicity and markers of liver function in patients with non alcoholic fatty liver disease

Protocol summary

Summary

The present study aiming to evaluate the effect of synbiotic yogurt consumption on hepatic echogenicity, liver enzymes, lipid profile, glycemic status, blood pressure, body composition, oxidative stress markers, glucagon like peptide-2, and complement C1q/tumor necrosis factor- α related protein-5 in patients with non alcoholic fatty liver disease. This study is a parallel randomized controlled clinical trial. 102 Patients will be randomly allocated into three groups, including two intervention groups and the control group. Exclusion criteria includes alcohol use, viral hepatitis, hepatocellular carcinoma, other causes of chronic liver disease, diabetes mellitus, untreated hypothyroidism, psychiatric disorder, kidney disease, pregnancy and lactation. The intervention groups will consume 300 grams per day of synbiotic or conventional yogurt in addition to usual treatment and control group will receive usual treatment for 24 weeks. Dietary assessment, anthropometric measurements, blood pressure, physical activity questionnaire and fasting blood sampling will be done at the weeks 0, 8, 16 and 24 of the trial and the results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020932417N2**

Registration date: **2017-03-12, 1395/12/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 2375

Email address

alizadeh.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2016-07-30, 1395/05/09

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic yogurt consumption on liver echogenicity and markers of liver function in patients with non alcoholic fatty liver disease

Public title

The effect of synbiotic yogurt on non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: contracting non alcoholic fatty liver disease and age of between 18 and 75. Exclusion criteria: alcohol use; viral hepatitis; hepatocellular carcinoma; other causes of chronic liver disease;

diabetes mellitus; untreated hypothyroidism; psychiatric disorder; kidney disease; pregnancy; and lactation.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Orjans valley, Resalat boulevard

City

Urmia

Postal code

Approval date

2016-06-11, 1395/03/22

Ethics committee reference number

umsu.rec.1395.113

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Fat free mass

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

BIA, percentage

2

Description

Fat mass

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

BIA, percentage

3

Description

Hepatic steatosis

Timepoint

Before Intervention and six months after Intervention

Method of measurement

Ultrasonography

4

Description

HDL cholesterol

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, mg/dl

5

Description

Triglyceride

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, mg/dl

6

Description

LDL cholesterol

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, mg/dl

7

Description

Total cholesterol

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, mg/dl

8

Description

Fasting blood sugar

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, mg/dl

9

Description

Serum Insulin

Timepoint

Before Intervention and six months after Intervention

Method of measurement

Radioimmunoassay, μ U/ml

10

Description

Alanine Aminotransferase

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, IU/Lit

11

Description

Aspartate transaminase

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, IU/Lit

12

Description

Alkaline phosphatase

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, IU/Lit

13

Description

Gamma Glutamyl transferase

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Enzymatic method, IU/Lit

14

Description

Total antioxidant capacity

Timepoint

Before Intervention and six months after Intervention

Method of measurement

ELISA method, μ M

15

Description

Total oxidant status

Timepoint

Before Intervention and six months after Intervention

Method of measurement

Enzymatic method, μ M

16

Description

Complement C1q/tumor necrosis factor- α related protein-5

Timepoint

Before Intervention and six months after Intervention

Method of measurement

ELISA method, mg

17

Description

glucagon like peptide-2

Timepoint

Before Intervention and six months after Intervention

Method of measurement

ELISA method, pg/ml

18

Description

Systolic blood pressure

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Mercury sphygmomanometer, mmHg

19

Description

Diastolic blood pressure

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Mercury sphygmomanometer, mmHg

20

Description

Weight

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

Scale, kg

21

Description

Height

Timepoint

Before intervention

Method of measurement

Stadiometer, mm

22

Description

Body mass index

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

weight (kg) / [height (m)]², kg/m²

23

Description

Carbohydrate Intake

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

gr/day

24

Description

Protein Intake

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

gr/day

25

Description

Fat Intake

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

gr/day

26

Description

Energy Intake

Timepoint

At weeks 0, 8, 16 and 24

Method of measurement

kcal/day

Secondary outcomes

empty

Intervention groups

1

Description

The second intervention group will be consume 300 grams per day conventional yogurt in addition to usual treatment for six months.

Category

Treatment - Other

2

Description

The first intervention group will be consume 300 grams

per day synbiotic yogurt in addition to usual treatment for six months.

Category

Treatment - Other

3

Description

The control group will receive usual treatment for six months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sahand clinic

Full name of responsible person

Dr. Kamran Shateri

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Urmia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

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 of Urmia 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

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

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

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

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Person responsible for updating data

Contact

Name of organization / entity

Uremia University of Medical Sciences

Full name of responsible person

Farnush Bakhshi Moghadam

Position

MS Student of nutrition

Other areas of specialty/work**Street address****City****Postal code****Phone**

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Fax**Email****Web page address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

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

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

City

Urmia

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