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 echogenisity, 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, µU/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, µM

15

Description
Total oxidant status
Timepoint
Before Intervention and six months after Intervention
Method of measurement
Enzymatic method, µM

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
ELIZA 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

City
Urmia

Postal code

Phone
+98 44 3275 2375

Fax

Email
alizadeh.m@umsu.ac.ir

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

Postal code

Phone
+98 44 3275 2375

Fax

Email
alizadeh.m@umsu.ac.ir

Web page address

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
00

Fax

Email

Web page address

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