

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparing the effect of probiotic and conventional yoghurt consumption on metabolic status and serum hs-CRP level, leptin and paraoxonase 1 enzyme activity in patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

This study is a randomized double-blind placebo controlled trial that subject from women aged 20-50 years (premenopausal) and men 20-65 years with BMI=25-40 kg/m² will be recruited from Sheykhorraeis clinic of Tabriz. The aim of the study is determining the effect of probiotic and conventional yoghurt consumption on metabolic status and serum hs-CRP level, leptin and paraoxonase 1 enzyme activity in patients with non-alcoholic fatty liver disease (NAFLD). Patients will be divided randomly to 2 groups; treatment and placebo. Treatment group receive 300 g of probiotic yoghurt 1.5% fat containing at least 107 cfu/g probiotic per day and placebo group 300 g of conventional yoghurt 1.5% fat for 8 weeks. Ultrasonography, Anthropometric measurements (weight, height), biochemical criteria including plasma level of Aspartat aminotransferase, Alanin aminotransferase, Total cholesterol, triglyceride, High density lipoprotein, Low density lipoprotein, Fasting blood glucose, Insulin resistance, Malondialdehyde, leptin hormone, hs-CRP and paraoxonase 1 enzyme activity appetite evaluation, 3 days of 24 hour food recall will be measured before and after treatment and will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205293664N7**

Registration date: **2012-06-17, 1391/03/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-17, 1391/03/28

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafrafm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of probiotic and conventional yoghurt consumption on metabolic status and serum hs-CRP level, leptin and paraoxonase 1 enzyme activity in patients with non-alcoholic fatty liver disease (NAFLD)

Public title

Effect of probiotic yoghurt in patients with non-alcoholic fatty liver disease (NAFLD)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who agree to participate in the study; women aged 20-50 years (premenopausal) and in men 20-65 years; BMI range between 25 to 40 kg/ m² and suffering from nonalcoholic fatty liver disease.

Exclusion criteria: suffering from gastrointestinal disease, diabetes and rheumatoid arthritis; receiving antibiotics during the two weeks before and during the study; follow the diet and weight loss; receiving supplements of vitamins, antioxidants, fiber and omega-3 within 3 weeks before baseline and during the study; presence of pregnancy or lactation or menopause; taking contraceptive drugs; liver transplantation; alcohol intake; any cause of chronic liver disease other than NAFLD, such as testing positive for hepatitis B, hepatitis C and autoimmune hepatitis - Immune; history of cancer and treatment; performing a complete intravenous feeding; rapid weight loss; cut part of the intestine and gastropathy; drugs such as corticosteroids, amiodarone, tamoxifen, cyclins, perhexiline, methotrexate, aspirin and hydralazine; presence of inherited Hemochromatosis (transferrin saturation greater than 45%) and Wilson's disease; Cholestatic liver disease; advanced liver disease; heart failure; thyroid (abnormal TSH) and renal disease; gastric bypass surgery and cachexia.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Vice-chancellor for research-Tabriz University of Medical Science

Street address

Golgasht street, Tabriz.East Azarbayjan

City

Tabriz

Postal code

51665-118

Approval date

2012-05-28, 1391/03/08

Ethics committee reference number

9135

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76

ICD-10 code description

Other diseases of liver

Primary outcomes

1

Description

Liver Enzymes(ALT,AST)

Timepoint

Baseline and at the end of intervention

Method of measurement

Autoanalyzer

2

Description

Total Cholesterol

Timepoint

Baseline and at the end of intervention

Method of measurement

Spectrophotometry

3

Description

Triglyceride

Timepoint

Baseline and at the end of intervention

Method of measurement

Spectrophotometry

4

Description

HDL

Timepoint

Baseline and at the end of intervention

Method of measurement

Spectrophotometry

5

Description

LDL

Timepoint

Baseline and at the end of intervention
Method of measurement
Friedewald Formula

6

Description

Insulin

Timepoint

Baseline and at the end of intervention

Method of measurement

ELIZA

7

Description

HOMA-IR

Timepoint

Baseline and at the end of intervention

Method of measurement

Formula

8

Description

Fasting Blood Sugar

Timepoint

Baseline and at the end of intervention

Method of measurement

spectrophotometry

9

Description

Malondialdehyde

Timepoint

Baseline and at the end of intervention

Method of measurement

Spectrophotometry

10

Description

hsCRP

Timepoint

Baseline and at the end of intervention

Method of measurement

immunoturbidometry

11

Description

Leptin

Timepoint

Baseline and at the end of intervention

Method of measurement

ELIZA

12

Description

activity of PON1 Enzyme

Timepoint

Baseline and at the end of intervention

Method of measurement

Spectrophotometry

13

Description

AST/ALT

Timepoint

Baseline and at the end of intervention

Method of measurement

Formula

Secondary outcomes

1

Description

Dietary Factors

Timepoint

Baseline and at the end of intervention

Method of measurement

3-day 24h dietary recalls

2

Description

Body Mass Index

Timepoint

Baseline and at the end of intervention

Method of measurement

Formula

3

Description

echogeneocity of liver tissue

Timepoint

Baseline and at the end of intervention

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: 300 gr probiotic yoghurt daily

Category

Other

2

Description

Placebo group: 300 gr conventional yoghurt daily

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sheykhorraeis clinic in Tabriz
Full name of responsible person
Safoora Nabavi
Street address
City
Tabriz

safoora.nabavi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Rafraf
Position
Assistant professor in Nutrition
Other areas of specialty/work
Street address
Health and Nutrition faculty, AttareNeishabouri
Avenue, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 914 314 5786
Fax
Email
rafrafm@tbzmed.ac.ir; safoora.nabavi@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research-Tabriz University of
Medical Science
Full name of responsible person
Alireza Ostadrahimi
Street address
Golgasht street, Tabriz.East Azarbayjan
City
Tabriz
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-Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Safoora Nabavi
Position
MSc student in community nutrition
Other areas of specialty/work
Street address
Health and Nutrition faculty, AttareNeishabouri
Avenue, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 918 372 9871
Fax
Email

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Safoora Nabavi
Position
MSc student in community Nutrition
Other areas of specialty/work
Street address
Health and Nutrition faculty, AttareNeishabouri
Avenue, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 918 372 9871
Fax
Email
safoora.nabavi@yahoo.com
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