

# 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/m<sup>2</sup> 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/ m<sup>2</sup> 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  
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Assistant professor in Nutrition  
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## 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**  
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**Full name of responsible person**  
Safoora Nabavi  
**Position**  
MSc student in community nutrition  
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## Person responsible for updating data

### 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*