

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Aug 2026

Comparing the effect of probiotic and conventional yoghurt consumption on serum level of adiponectin in patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

objectives: Effect of probiotic yogurt and conventional yogurt on serum adiponectin levels in patients with nonalcoholic fatty liver disease and compared them with each other Design: A double-blind randomized controlled trial Setting and conduct: Selected samples are divided into two groups: intervention and placebo. 8-week intervention takes place. Ultrasound, anthropometric measurements (weight, height), serum adiponectin levels and the three day 24- hour dietary recall at baseline and again at the end of the study will be assessed and compared between the two groups. Participants including major eligibility criteria: Women aged 20-50 years (premenopausal) and in men 20-65 years with body mass index (BMI) range between 25 to 40 kg/ m2 that suffer from Nonalcoholic fatty liver disease Participants including major eligibility criteria: Women aged 50-20 years (premenopausal) and men 65-20 years 40-25 years with a body mass index referred to Sheikh Alrmys city of Tabriz Interventions: intervention group: 300 grams probiotic yoghurt 1.5% fat daily and placebo group 300 grams of conventional yogurt 1.5% fat daily. main outcome : Serum adiponectin levels

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210313664N8**
Registration date: **2012-11-28, 1391/09/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Maryam Rafrat

Name of organization / entity

Tabriz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

nutrition Research center, 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 serum level of adiponectin in patients with non-alcoholic fatty liver disease (NAFLD)

Public title

Comparing the effect of probiotic and conventional yoghurt consumption 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; suffering from Nonalcoholic fatty liver disease
Exclusion criteria: suffering from gastrointestinal disease; diabetes and rheumatoid arthritis; Receiving Antibiotics during the two weeks before the study 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; cachexia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

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

Ethics Committee of Tabriz University of Medical Science

Street address

Golgasht street, Tabriz.East Azarbayjan

City

Tabriz

Postal code

Approval date

2012-10-30, 1391/08/09

Ethics committee reference number

9135

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

k75.8

ICD-10 code description

nonalcoholic steatohepatitis

Primary outcomes

1

Description

adiponectin

Timepoint

Baseline and at the end of intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 300 g probiotic yogurt

Category

Other

2

Description

Placebo group: 300 g conventional yoghurt

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykhorrakis clinic in Tabriz

Full name of responsible person

Safoora Nabavi

Street address

City

Tabriz

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

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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 science

Full name of responsible person

Vice-chancellor for research-Tabriz University of Medical Science

Position

Assistant professor in Nutrition

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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