Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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 Alryys city of Tabriz Interventions: intervention group: 300 grams probiotic yoghut 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

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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
Sheykhorraeis 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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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