

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of two isocaloric energy-restricted diets on non-alcoholic fatty liver disease patients: a cross over randomized controlled trial

Protocol summary

Summary

The aim of this study is to examine the effect of two isocaloric energy-restricted diets on non-alcoholic fatty liver disease patients. Maximum 40 Patients using NAFLD Registration research data file in Tabriz university who would like and have not diseases like renal and pulmonary diseases,...and not use hepatotoxic drugs and with moderate activity level will be selected. Patients will be randomly allocated into two diets with considering BMI and sex matching. Diet1 and Diet2 will be followed for 6 weeks. Daily energy requirement will be estimated based on age, sex, height, ideal body weight and physical activity level. Diets will be as follows: Diet 1: C 55%, F 25%, P 20% and Diet 2: C 40%, F 40% and P 20%. After the 6-week period, patients will start a 14-day washout period and then, in a cross-over manner, patients will be switched for the second 6-week period. Three days weighing food record questionnaires will be fulfilled. Obesity indices (inc. Body mass index, waist circumference , waist to hip ratio), fasting levels of ALT, AST, ALP, lipid profiles (inc. TC, HDL-C, LDL-C, TG, LP(a)), insulin resistance and liver echogenicity using sonography will be assessed at baseline, and end of each period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811203320N1**
Registration date: **2010-03-14, 1388/12/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-14, 1388/12/23

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Liver and gastrointestinal diseaese research center, Nutritional research center, Tabriz university of medical sciences

Expected recruitment start date

2009-04-14, 1388/01/25

Expected recruitment end date

2009-09-22, 1388/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of two isocaloric energy-restricted diets on non-alcoholic fatty liver disease patients: a cross over randomized controlled trial

Public title

Effect of two different diets on non-alcoholic fatty liver disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Liver steatosis on sonographic image, 20-55 years old, BMI $\geq$ 25, moderately activity.
Exclusion criteria: Alcohol intake more than 20g/d, gestation or lactation, very active or inpatients, hypertension, Cardiovascular disease, Pulmonary disease, renal disease, liver transplantation, other liver diseases and chronic or acute liver disease(Hepatitis A,B, ...), bilious impairments, cancers, inheritance diseases, using drugs like blood pressure lowering, statins, insulin sensitivity enhancer, hepatotoxic drugs and estrogen

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

Approval date

2010-02-04, 1388/11/15

Ethics committee reference number

8812

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

Liver enzymes

Timepoint

begin and end of each phase

Method of measurement

Autoanalyser

Secondary outcomes

1

Description

Liver steatosis

Timepoint

begin and end of first phase(first 6 weeks) and end of second phase(second 6 weeks)

Method of measurement

Liver sonography

Intervention groups

1

Description

high carbohydrate diet (55%)

Category

Lifestyle

2

Description

high fat diet (40%)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Seikh alraees clinic

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Liver and gastrointestinal disease research center
Full name of responsible person
 Dr. Mohammad Hossein Somi
Street address
 Imam Reza hospital
City
 Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Liver and gastrointestinal disease research center
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
 Nutritional research center
Full name of responsible person
 Dr. Alireza Ostad Rahimi
Street address
 Health & Nutrition Faculty
City
 Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Nutritional research center
Proportion provided by this source
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

3

Sponsor
Name of organization / entity
 Vice chancellor for research of Tabriz university of medical sciences
Full name of responsible person
 Dr. Rasoul Azarfarin
Street address

Tabriz university of medical sciences
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 of Tabriz university of medical sciences
Proportion provided by this source
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

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Health & Nutrition Faculty of Tabriz university of medical sciences
Full name of responsible person
 Dr. Mehrangiz Ebrahimi
Position
 Ph.D of Nutrition Epidemiology
Other areas of specialty/work
Street address
 Health & Nutrition Faculty of Tabriz university of medical sciences
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 Tabriz
Postal code
Phone
 +98 41 1335 7581
Fax
Email
 ebrahimim@hotmail.com
Web page address

Person responsible for updating data

Contact

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