Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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ebrahimimamagani@tbzmed.ac.ir

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>=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 commitee 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 diseaese 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 diseaese 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

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Phone

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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