Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of weight loss diet based on DASH diet on proxidant-antioxidant balance levels, lipid profile, liver fibrosis score, appetite status and quality of life in patients with non-alcoholic fatty liver

Protocol summary

Study aim

The aim of the present study is to investigate the effect of weight loss diet based on DASH diet on Pro-Oxidant-Antioxidant Balance (PAB) , lipid profile, liver fibrosis score, appetite status and quality of life among patients with non-alcoholic fatty liver disease.

Design

Double blind randomized controlled clinical trial

Settings and conduct

The patients who newly diagnosed as NAFLD and met the inclusion criteria will be included in the study and then randomly assigned into the intervention and control groups.

Participants/Inclusion and exclusion criteria

44 patients with grade 1 and 2 NAFLD who aged 20-50 years with BMI 30-40 kg / m2 will be included in the study. Those with alcohol consumption, pregnancy, lactation, menopause, being an athlete, having a weight loss diet 3 months before the study, the use of lowering blood sugar, lipid drugs, antibiotics , corticosteroids and antioxidant supplements , suffering from metabolic disease inc. cardiovascular, renal, liver, thyroid, autoimmune diseases, kidney stones and cancers will be excluded.

Intervention groups

The intervention group will receive a weight loss diet based on the DASH diet while the control group will receive the usual weight loss diet.

Main outcome variables

Nutritional status (anthropometric indices , and energy and macronutrients intakes), ultrasonography findings, serum levels of Pro-Oxidant-Antioxidant Balance (PAB), lipid profile, liver fibrosis score, appetite status and quality of life

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20100209003320N19**
Registration date: **2021-06-06, 1400/03/16**
Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**
Update count: **0**

Registration date

2021-06-06, 1400/03/16

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-07, 1400/03/17

Expected recruitment end date

2021-10-10, 1400/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of weight loss diet based on DASH diet on proxidant-antioxidant balance levels, lipid profile, liver fibrosis score, appetite status and quality of life in patients with non-alcoholic fatty liver

Public title

The effect of DASH diet on NAFLD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 20-50 Grade 1 and 2 NAFLD disease Body mass index in the range of 30-40 Kg / m2 Willingness to cooperate

Exclusion criteria:

Alcohol consumption Pregnancy Lactation Menopause Being an athlete Having a weight loss diet 3 months before the study The use of lowering blood sugar, lipid drugs , antibiotics , corticosteroids and Antioxidant supplement Suffering from metabolic diseases inc. cardiovascular, renal, liver, thyroid, autoimmune diseases, kidney stone and cancers

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

44 eligible patients will be randomly allocated to intervention and control groups using random blocks by an independent third party who is blinded to the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the main investigators (patients and investigators),will be blinded to the type of diet (DASH diet or the usual weight loss diet) received by each patient and group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neishabouri Ave., Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

51666-14711

Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.TBZMED.REC.1400.009

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

Energy and macronutrients intakes

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

The intake of energy and macronutrients of the subjects using a 3-day food record questionnaire analyzed by the nutritionist 4 software.

2

Description

Anthropometric Indices

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Measing height and weight without shoes and with minimum clothes using Seca stadiometer. Waist and hip circumferences will be measured using a tape and then body mass index (BMI) will be estimated by dividing weight (kg) to height squared (m2)

3

Description

Liver enzymes (ALT , AST)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

4

Description
albumin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

5

Description
platelet count
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
cell counter

6

Description
Pro-Oxidant Antioxidant Balance (PAB)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA

7

Description
lipid profile
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic colorimetric method

8

Description
liver fibrosis score
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Liver fibrosis score formula

9

Description
Blood glucose
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

10

Description
Appetite status
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Validated appetite questionnaire

11

Description
quality of life
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will receive the DASH-based weight loss diet for 8 weeks.
Category
Lifestyle

2

Description
Control group: Patients in this group will receive the usual weight loss diet for 8 weeks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikhoreis Clinic
Full name of responsible person
Dr. Mehrangiz Ebrahimimamagani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostad Rahimi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Taghi Badali
Position
MSC student of nutrition sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Access starting 12 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions .

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers , for conducting meta-analysis .

From where data/document is obtainable

Taghi Badali, E-mail address:Tbadali17@gmail.com, cellphone number: 0098 9144565411

What processes are involved for a request to access data/document

The applicant should provide a brief description of the aims and methods of his Meta-analysis . His request will be assessed and , if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 15 days.

Comments