

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of DASH-based weight loss diet on serum Lipopolysaccharide level and meta-inflammation status among patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

The aim of the present study is to investigate the effect of DASH-based weight loss diet on serum Lipopolysaccharide level and meta-inflammation status among patients with non-alcoholic fatty liver disease.

Design

Randomized double blind clinical trial with two arm parallel groups

Settings and conduct

Volunteer patients in the Tabriz city whose disease is diagnosed by a newly diagnosed specialist will be included in the study and met the inclusion criteria and will be randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria

44 patients with grade 1 and 2 NAFLD aged 20-50 years and BMI 30-40 kg / m² will be included in the study. Alcohol consumption, pregnancy, breastfeeding , menopause , being an athlete , having a weight loss diet 3 months before the study , the use of lowering blood sugar , lipid , blood pressure drugs , antibiotics and corticosteroids , suffering from metabolic disease , cardiovascular , renal , kidney stone , liver disease , thyroid disease , autoimmune and cancer are among the exclusion criteria.

Intervention groups

Patients in the intervention group will receive a weight loss diet based on the DASH diet. Patients in the control group will receive the usual weight loss diet.

Main outcome variables

Nutritional status (anthropometric indices , and calorie and macronutrients intake), Serum levels of liver enzymes (ALT, AST) and ultrasound findings , Serum levels of lipopolysaccharides(LPS) , Meta-inflammation status (MCP-1, TLR-4)

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20100209003320N17**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **retrospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

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

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of DASH-based weight loss diet on serum Lipopolysaccharide level and meta-inflammation status among patients with non-alcoholic fatty liver disease

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 Breastfeeding Menopause Being an athlete Having a weight loss diet 3 months before the study The use of lowering blood sugar , lipid , blood pressure drugs , antibiotics and corticosteroids Suffering from metabolic disease , cardiovascular , renal , kidney stone , liver disease , thyroid disease , autoimmune and cancer

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 placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main investigators (including the student and her supervisors and adviser professors), as well as the patients will be blinded to the type of diet (DASH diet or the usual weight loss diet) received by each 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

5166/1573113

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.TBZMED.REC.1398.741

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

Calorie and macronutrients intake

Timepoint

Baseline and 4 weeks after the intervention and 8 weeks after the intervention

Method of measurement

The intake of calorie and macronutrients from the diet of the subjects with using a 3 day food record questionnaire and analysis by the nutritionist 4 program.

2

Description

Anthropometric Indices

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Measurement of waist and hip circumference by a tape measure and body mass index

(BMI) by dividing weight (kg) by height squared (m²)

3

Description

Liver enzymes (ALT , AST)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Enzymatic method

4

Description

Serum levels of lipopolysaccharide

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

5

Description

Inflammatory indices (MCP-1 , TLR-4)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

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

Sheikholrais Clinic

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

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Azadi street

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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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Faculty of Nutrition and Food Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Farnaz Rouhollahzadegan

Position

MSC student of nutrition sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Faculty of Nutrition and Food Sciences.,Attar
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farnazrz69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Mehrangiz Ebrahimi Mamagani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Ms.Farnaz Rouhollahzadegan, E-mail
address:farnazrz69@gmail.com, cellphone number: 0098
9014574722

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