Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 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

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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
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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?
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

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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
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