

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 / m<sup>2</sup> 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)

##### Phone

+98 41 1335 1113

##### Email address

brahimimamagani@tbzmed.ac.ir

##### 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 / m<sup>2</sup> 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 (m<sup>2</sup>)

### 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

##### **Street address**

Azadi street

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5185747731

##### **Phone**

+98 41 3335 7314

##### **Email**

ebrahimimamagani@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Alireza Ostad Rahimi

##### **Street address**

Faculty of Nutrition and Food Sciences

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614711

##### **Phone**

+98 41 3335 2292

##### **Email**

nut-rc@tbzmed.ac.ir

#### **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

**Street address**

Faculty of Nutrition and Food Sciences.,Attar  
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**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**

Nutrition

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farnaz Rouhollahzadegan

**Position**

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**Email**

farnazrz69@gmail.com

**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**