Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of DASH diet on hepatic fibrosis, hepatic steatosis, liver enzymes, insulin resistance and oxidative stress in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effect of DASH diet on hepatic fibrosis, hepatic steatosis, liver enzymes, insulin resistance and oxidative stress in patients with non-alcoholic fatty liver

Design
Randomized clinical trial

Settings and conduct
The present study is a randomized controlled clinical trial to evaluate the effect of DASH counseling and diet on insulin resistance factors in patients with non-alcoholic fatty liver disease, which is referred to non-alcoholic fatty liver patients referred to the clinic Alikhani diabetes will be performed in Yazd for 12 weeks. In addition, people with diabetes receive their routine treatment under the supervision of a specialist. Smoking is a confounding factor and is eliminated in statistical models. Participation in the study is completely free and is managed by explaining in detail the study process, goals, benefits and limitations and obtaining written and oral consent with the patient's signature or, if necessary, by the patient's companion.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. People 18 to 70 years old 2. People with body mass index 25 to 40 3. Diagnosis based on liver fiberoscan 4. Have informed consent. Exclusion criteria: 1. Pregnancy and lactation 2. Hereditary hemochromatosis 3. History of gingival or gastroplasty bypass surgery 4. Use of hepatotoxic drugs such as calcium channel blocker and high doses of synthetic estrogens 5. Patients with hypothyroidism 6. Kushing syndrome 7.Kidney failure and kidney stones 8. Cardiovascular disease 9. People with a history of hepatitis B and C 10. Wilson disease

Intervention groups
DASH diet recipient group

Main outcome variables
Hepatic fibrosis, hepatic steatosis and liver enzymes

General information

Reason for update
We revised title and sample size. In addition, we added outcomes.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170117032026N3**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-25, 1401/10/04**
Update count: **1**

Registration date
2022-02-06, 1400/11/17

Registrant information

Name
Mahdie Hoseinzade

Name of organization / entity
Shahid Sadoughi University Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 9110

Email address
hoseinzadeh@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of DASH diet on hepatic fibrosis, hepatic steatosis, liver enzymes, insulin resistance and oxidative stress in patients with non-alcoholic fatty liver disease

Public title

Effect of DASH diet in patients with non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: 1. People 18 to 70 years old 2. People with body mass index 25 to 40 3. Diagnosis based on liver fibroscan 4. Have informed consent.

Exclusion criteria:

1. Pregnancy and lactation 2. Hereditary hemochromatosis 3. History of gingival or gastroplasty bypass surgery 4. Use of hepatotoxic drugs such as calcium channel blockers and high doses of synthetic estrogens 5. Patients with hypothyroidism 6. Cushing's syndrome and 7. Kidney failure Kidney stones 8. Cardiovascular disease 9. People with a history of hepatitis B and C 10. Wilson disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The distribution of people between groups is done randomly and a random allocation table created using a computer is used. Randomization is block type and classification based on gender and body mass index. In this study, individuals will be divided into two groups of intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Public Health, Shahid Sadoughi University of Medical Sciences,

Street address

Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.SSU.SPH.REC.1400.145

2

Ethics committee

Name of ethics committee

Ethics committee of School of Public Health, Shahid Sadoughi University of Medical Sciences,

Street address

Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City

Yazd

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Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.SSU.SPH.REC.1400.144

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

DB92.Y

ICD-10 code description

Non-alcoholic fatty liver disease

Primary outcomes

1

Description

Alanine Aminotransferase

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Special kits

2

Description
Aspartat transaminase
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kits

3

Description
Gamma-glutamyl transpeptidase
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kits

4

Description
Hepatic fibrosis
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Fibroscan

5

Description
Hepatic steatosis
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Fibroscan

Secondary outcomes

1

Description
Weight, fat mass, fat free mass, RMR, body mass index and visceral fat
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Omron digital Scale

2

Description
Waist,Hip circumference
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Meter

3

Description
Diastolic blood pressure
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Sphygmomanometer

4

Description
Systolic blood pressure
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Sphygmomanometer

5

Description
Fasting blood sugar
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Special kit

6

Description
Insulin
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Special kit

7

Description
Total antioxidant capacity
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

8

Description
Catalase
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

9

Description
Superoxide dismutase
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

10

Description
PAB
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement

Special kit

11

Description
High sensitivity C-reactive protein
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

12

Description
Triglyceride
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

13

Description
Total cholesterol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

14

Description
High density lipoprotein cholesterol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

15

Description
Low density lipoprotein cholesterol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Special kit

16

Description
Homeostatic model assessment of insulin resistance
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Formula

17

Description
Insulin sensitivity check index
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Formula

Intervention groups

1

Description
DASH (Dietary Approaches to Stop Hypertension) diet. This diet contains 52 to 55% carbohydrates, 16 to 18% protein and 30% fat. The DASH diet is rich in fruits, vegetables, whole grains and low-fat dairy products, and is low in saturated fat, cholesterol and refined grains. Calories needed by each patient are estimated based on basal metabolic rate (using the Harris-Benedict equation) and levels of physical activity and energy from food metabolism. Everyone in the study is overweight or obese, and for these people the calorie limit of 500 to 700 kcal is less than the calculated energy requirement for each person. 500 kcal for those with a BMI in the range of 25-31 kg / m2 and 700 kcal for those with a BMI of more than 31 kg / m2 will be deducted from the total energy required by each person. An alternative list is provided to patients while educating the patient to facilitate food selection and to observe the principle of diversity between the components of each food group.
Category
N/A

2

Description
Standard diet
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetes Center (Ali Khani)
Full name of responsible person
Mohammad Reza Aghaei
Street address
Bahonar Square
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0215
Email
drs@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Mahdie Hoseinzadeh
Street address
Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2232
Email
hoseinzade.mahdie@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr Mahdie Hoseinzadeh
Position
Phd of nutritin
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2232
Email
hoseinzade.mahdie@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Mahdie Hoseinzadeh
Position
Phd of nutritin
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2232
Email
hoseinzade.mahdie@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Mahdie Hoseinzadeh
Position
PhD of nutrition science
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2232
Email
hoseinzade.mahdie@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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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