Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on cardiometabolic parameters, oxidative stress and inflammatory markers, hepatic enzymes, and fatty liver severity in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on cardiometabolic parameters, oxidative stress and inflammatory markers, hepatic enzymes, and fatty liver severity in patients with non-alcoholic fatty liver disease

Design

The clinical trial has a control group, with 3 parallel groups (40 in each group), single blinded, randomized by random number table method

Settings and conduct

The number of 120 eligible patients for the study (40 in each group) will be selected.Then the subjects will be divided into three groups by permuted block randomization.The three groups include: dietary approaches to stop hypertension (DASH) diet, Hypocaloric diet, and DASH + Hypocaloric diet. The diet will be written to each individual. In this way, the required energy will be calculated based on Harris Benedict formula, In Group 1 the required energy will be determined and without deduction of energy units of each food groups will be determined based on the DASH diet. In Group 2 and 3 the rate of 500 kcal will be deducted, then units of each food groups will be determined based on a regular diet in group 2 and DASH diet in group 3. After 3 months of intervention, all groups will be compared for their changes in cardiometabolic parameters, oxidative stress, inflammatory markers, hepatic enzymes, and fatty liver severity.

Participants/Inclusion and exclusion criteria

Inclusion criteria: NAFLD patients should have BMI more than 25 exclusion criteria: Patients with dire diseases, Pregnancy, Alcohol consumption

Intervention groups

The subjects divide into 3 groups, Group 1: receiving dietary approaches to stop hypertension (DASH) diet, Group 2: receiving hypocaloric diet, Group 3: receiving hypocaloric DASH diet

Main outcome variables

Cardiometabolic parameters; Oxidative stress and inflammatory markers; Hepatic enzymes; Fatty liver severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121029011307N2**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **retrospective**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Zeynab Hatami Zargaran

Name of organization / entity

Health and Nnutrition School, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01
Expected recruitment end date
2019-07-23, 1398/05/01
Actual recruitment start date
2019-07-24, 1398/05/02
Actual recruitment end date
2019-08-24, 1398/06/02
Trial completion date
2019-12-31, 1398/10/10

Scientific title
Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on cardiometabolic parameters, oxidative stress and inflammatory markers, hepatic enzymes, and fatty liver severity in patients with non-alcoholic fatty liver disease

Public title
Comparison of the effect of dietary approaches to stop hypertension (DASH) diet to improve non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a non alcoholic fatty liver disease (NAFLD) to diagnose a doctor (using Ultra Ultrasound) willing to participate in the study
Exclusion criteria:
Patients with cardiovascular disease, liver disease (cirrhosis, alcoholic liver disease, viral hepatitis, autoimmune hepatitis, primary bile cirrhosis, bile obstruction, liver damage induced by hereditary hemochromatosis drugs, sclerosis, and α-antitrypsin deficiency), other dire diseases Such as cancer, kidney failure and... Celiac Pregnancy, lactation Taking medications that cause fatty liver (methotrexate, tamoxifen, Oalprowat, etc.) Taking blood lipid-lowering drugs Malnutrition Having certain diets like vegetarian and raw veganism Alcohol consumption
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization: First, the list of participants was provided according to their referral. Then all possible sequences that can be written with three groups, were written on paper (for 3 groups 6 sequences can be written). Then one of the numbers from 1 to 6 was considered for each sequence, for example for the ABC sequence 1 and for the ACB sequence 2 and as such, one of the numbers 3 to 6 was considered for the other 4 sequences. Then, using random number table, the random numbers were selected from one point to the left or right. Wherever the random number was 1 to 6, the corresponding sequence was recorded on the paper, and wherever the numbers were 0 or 7, 8, 9, the next number that was between 1 to 6 was considered. This method continued until groups for the total number of participants were determined. Then, the names of subjects on the list were allocated to the specific groups according to the sequence of groups which had been determined by the above mentioned procedure.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are unaware of the differences in the incoming regimes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Reyhaneh building, 8/6 Alley, Southern Hemmat Avenue
City
Shiraz
Province
Fars
Postal code
7188776461
Approval date
2019-04-22, 1398/02/02
Ethics committee reference number
IR.SUMS.REC.1398.314

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
Fatty liver severity
Timepoint
At the beginning of the study (before intervention) and three months after the beginning of the intervention
Method of measurement
Using Ultrasound

Secondary outcomes

1

Description
Isoprostane 8
Timepoint
At the beginning of the study (before intervention) and three months after the beginning of the intervention
Method of measurement
Enzyme-linked immunosorbent kit

2

Description
Interleukin 6
Timepoint
At the beginning of the study (before intervention) and three months after the beginning of the intervention
Method of measurement
Enzyme-linked immunosorbent kit

3

Description
C-Reactive Protein
Timepoint
At the beginning of the study (before intervention) and three months after the beginning of the intervention
Method of measurement
Enzyme-linked immunosorbent kit

4

Description
Aspartate aminotransferase
Timepoint
At the beginning of the study (before intervention) and three months after the beginning of the intervention
Method of measurement
Calorimetry method

Intervention groups

1

Description
Intervention group 1: Receiving dietary approaches to stop hypertension diet(DASH). In this group, the required energy of each person will be determined based on Harris Benedict formula and without deduction of energy, units of each food groups will be determined based on DASH diet. DASH diet is rich in fruits, vegetables, whole grains, low-fat dairy foods and is limited in saturated fatty acids, total fat and cholesterol, refined cereals and sugar sweetened drinks with an overall 2400 mg per day sodium intake.
Category
Treatment - Other

2

Description
Intervention group 2: Receiving hypocaloric diet. In this group, the required energy of each person will be determined based on Harris Benedict formula, the rate of 500 kcal will be deducted then units of each food groups will be determined based on a regular diet.
Category
Treatment - Other

3

Description
Control group: Receiving dietary approaches to stop hypertension diet (DASH) hypocaloric diet. In this group, the required energy of each person will be determined based on Harris Benedict formula, the rate of 500 kcal will be deducted then units of each food groups will be determined based on DASH diet.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza clinic
Full name of responsible person
Zeinab Hatami Zargaran
Street address
Reyhaneh building, 8/6 Alley, Southern Hemmat Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
SG-97-37
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Zeinab Hatami Zargaran
Position
PhD student
Latest degree
Master
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
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