Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of the hypocaloric DASH diet (Dietary Approaches to Stop Hypertension) on liver enzymes, lipid profiles and insulin resistance in patients with fatty liver

Protocol summary

Study aim

The aim of this study is to determine the effects of the hypocaloric Dietary Approaches to Stop Hypertension (DASH) diet on insulin resistance, inflammatory factor and biomarkers of oxidative stress in patients with fatty liver.

Design

Study design: parallel single-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 patients with fatty liver among subjects of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with laboratorial and sonographical criteria of fatty liver and aged 25 to 75 years will be included in this study. Exclusion criteria: Consumption of alcohol, pregnancy and lactation, hereditary hemochromatosis, history of jejunoileal bypass surgery or gastroplasty, taking hepatotoxic drugs such as calcium channel blocker and high doses of synthetic estrogens, history of hypothyroidism, cushing's syndrome, renal failure and kidney stones.

Intervention groups

Intervention: Patients will be assigned to receive either the DASH diet (intervention group) or the standard diet (control group). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles, inflammatory factor and biomarkers of oxidative stress. Start and End Date of Intervention: 2 months

Main outcome variables

Outcomes: Alanine aminotransferase (primary outcome), and clinical and metabolic profiles (secondry outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201311215623N14**
Registration date: **2013-12-11, 1392/09/20**
Registration timing: **prospective**

Last update: **2019-09-28, 1398/07/06**
Update count: **1**

Registration date

2013-12-11, 1392/09/20

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of the hypocaloric DASH diet (Dietary Approaches to Stop Hypertension) on liver enzymes, lipid profiles and insulin resistance in patients with fatty liver

Public title
Effect of low caloric diet in fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects aged 25-75 years All patients with laboratorial and sonographical criteria of fatty liver.

Exclusion criteria:
Consumption of alcohol Pregnancy and lactation Hereditary hemochromatosis History of jejunoileal bypass surgery or gastroplasty Taking hepatotoxic drugs such as calcium channel blocker and high doses of synthetic estrogens History of hypothyroidism Cushing's syndrome Renal failure and kidney stones

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take DASH (n = 30) or control (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants and the assessors of the outcomes are unaware of the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences

Street address
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Approval date
2013-11-20, 1392/08/29

Ethics committee reference number
3462/1/5/29/P

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
ALT

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic

Secondary outcomes

1

Description
AST

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic

2

Description
Insulin

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa

3

Description
Hs-CRP
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

4

Description
Total Antioxidant Capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

5

Description
Fasting plasma glucose
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

6

Description
Triglycerides
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

7

Description
HDL-cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

8

Description
Total cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

9

Description
Nitric oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

10

Description
Malondialdehyde
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

11

Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

12

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa kit

13

Description
Grade of fatty liver
Timepoint
Baseline and End-of-trial
Method of measurement
Sonography

Intervention groups

1

Description
Intervention group: DASH diet, 6 serving vegetables, 6 serving fruits, rich in fiber and whole grains, daily for 8 weeks
Category
Other

2

Description
Control group: Standard diet, 4 serving vegetables, 4 serving fruits, rich in protein, daily for 8 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi outpatient Clinic
Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
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
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