

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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 (secondary 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)

Phone

+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

Isfahan

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

Zatollah Asemi
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Bolvar Ghotbe Ravandi, Kashan
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PhD of Nutrition
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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
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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

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Full name of responsible person
Zatollah Asemi
Position

Person responsible for scientific inquiries

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Fax**Email**

asemi_z@kaums.ac.ir

Web page address**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