Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing the therapeutic effects of lacto-Ovo-vegetarian and standard diet on the lipid profile, liver enzymes, and sonographic results of obese and overweight patients with nonalcoholic fatty liver disease: A randomized controlled trial.

Protocol summary

Study aim
This study has intended to compare the therapeutic effects of two type of calorie restricted diets including Lacto-Ovo-Vegetarian and standard diet on the lipid profile, liver enzymes, and sonographic outcomes of the obese and overweight patients with nonalcoholic fatty liver disease.

Design
In this research, 80 nonalcoholic fatty liver disease referring to khorshid clinic were chosen purposefully and a code was allocated to each one of them.then, patient were randomly divided into two control and intervention groups

Settings and conduct
Data collection will be conducted in the specialist's clinic of Khorshid hospital of Isfahan. Randomization will be conducted through a permuted block randomization of with size 2. Patients will be allocated between groups (1) and (2). Group (1) are the recipients of Lacto-ovo-vegetarian diet, and the group (2) consists of the recipients of a standard diet. At the beginning of the study, a blood sample and sonographic liver assessments will be derived from all patients. Based on the participants' BMI, 200-500 Kcal will be reduced from the energy requirements and will be provided in a weekly dietary menu to both groups. Outcomes of the disease will be compared by a blood sample test and liver sonographic assessments, after 12-weeks of interventions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Over-weight or obese patients with the nonalcoholic fatty liver disease confirmed with imaging techniques. exclusion criteria: Alcohol consumption; Pregnant and lactating women; Any known forms of hepatic or metabolic disease except Non alcoholic fatty liver disease;Using nutrition supplements;vegetarian diets; Hormone Therapy

Intervention groups
Intervention groups: patients who follow lacto ovo vegetarian diets Control groups: patients who follow normal diets

Main outcome variables
liver enzymes, lipid profile, sonographic outcomes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140208016529N2**
Registration date: **2018-05-31, 1397/03/10**
Registration timing: **retrospective**

Last update: **2020-08-01, 1399/05/11**
Update count: **1**

Registration date
2018-05-31, 1397/03/10

Registrant information

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Mohammad hassan Entezari

Name of organization / entity
Isfahan university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-30, 1396/10/09
Expected recruitment end date
2018-03-17, 1396/12/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the therapeutic effects of lacto-Ovo-vegetarian and standard diet on the lipid profile, liver enzymes, and sonographic results of obese and overweight patients with nonalcoholic fatty liver disease: A randomized controlled trial.

Public title
the effect of lacto ovo vegetarian and normal diets in nonalcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Over-weight or obese patients with the nonalcoholic fatty liver disease confirmed with imaging techniques increased levels of liver enzymes (serum levels of alanine aminotransferase and aspartate aminotransferase more than 40 U/L); Body Mass Index (BMI) of them is greater than 24.9 and lower than 40
Exclusion criteria:
Alcohol consumption Pregnant and lactating women Any known forms of hepatic or metabolic disease except NAFLD, such as hereditary hemochromatosis, Wilson's disease, cirosis, other metabolic disease history of gastric bypass or intestine surgery Taking hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine and anti inflammatory drugs; Using nutrition supplements or vegetarian diets Hormone Therapy Patients with a history of hypothyroidism, Cushing's syndrome renal failure kidney stones. Participants with less than 80% of adherence to the dietary plan are going to be excluded.
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a randomized controlled clinical trial. Randomization will be conducted through a permuted block randomization with size 2 and Participants will be allocated between groups 1 and 2. Group (1) are the recipients of a calorie restricted Lacto-ovo-vegetarian diet and the group (2) are the recipients of a calorie restricted standard diet.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Isfahan University of Medical Sciences
Street address
Department of Clinica Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan
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Province
Isfehan
Postal code
8174673461
Approval date
2017-06-14, 1396/03/24
Ethics committee reference number
IR.MUI.REC.1396.3.249

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver Disease.
ICD-10 code
K75.81
ICD-10 code description
Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
Liver enzymes (ALT, AST, ALP)
Timepoint
The first day of the study and the last day of 12th week
Method of measurement
Using Microgram/ml - laboratory kit

2

Description

Lipid profile (TG, LDL, HDL, Total cholestrol)

Timepoint

The first day of the study and the last day of 12th week

Method of measurement

laboratory kit

3

Description

Liver steatosis index

Timepoint

The first day of the study and the last day of 12th week

Method of measurement

Sonography

Secondary outcomes

1

Description

Waist to hip ratio

Timepoint

The first day of the study and the last day of 12th week

Method of measurement

Non-stretchable tape without any pressure

2

Description

Body Mass Index (BMI)

Timepoint

The first day of the study and the last day of 12th week

Method of measurement

Weight (kilograms) divided by the square of height (meters)

3

Description

Sistolic and diastolic blood pressure

Timepoint

The first day of the study and the last day of 12th week

Method of measurement

By mercury sphygmomanometer

Intervention groups

1

Description

The energy requirements of intervention group are calculated with Mifflin-St Jeor equation on the basis of weight, height, age, and sex of each participant. Take into account the patient's condition, 200-500 Kcal energy is decreased from the total energy requirements. A 7 days' dietary plan will be given to each participants including main meals and snakes for 12 consecutive weeks. Dietary plan of the intervention group has been designed based on lacto-ovo-vegetarian diet which refers to the meats elimination (red meats, poultry, fishes, shrimps, ...).

Category

Treatment - Other

2

Description

The energy requirements of the control group are calculated with the Mifflin-St Jeor equation based on the weight, height, age, and sex of each participant. Take into account the patient's condition, 200-500 Kcal energy is decreased from the total energy requirements. A 7 days' dietary plan will be given to each participants including main meals and snakes for 12 consecutive weeks. The dietary plan of the control group considered to be a standard diet which all patients in the will be allowed to consume any foodstuff including all types of meats.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

khorshid Hospital

Full name of responsible person

Mohammad hassan entezari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research, Isfahan 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
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available