Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of fruit rich diet on liver steatosis, liver enzymes, insulin resistance, lipid profile, and anthropometric measurements in patient with non alcoholic fatty liver disease

Protocol summary

Study aim

Determination of the effect of fruit rich diet on hepatic steatosis, liver enzymes, insulin resistance, lipid profile and anthropometric indices in patients with non-alcoholic fatty liver.

Design

Not blinded randomized clinical trial with control group, with parallel design, on 70 patients, the Stratified Block Randomization program was used for randomization.

Settings and conduct

The study will be performed on patients with non-alcoholic fatty liver referred to the gastrointestinal clinic at Imam Khomeini Hospital in Urmia. 35 patients were randomly assigned to each group.The intervention group along with the usual treatment will be recommended to consume at least 4 serving of fruit per day and the control group in addition to the usual treatment will be recommended to consume no more than 2 serving of fruit per day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age: more than 18 years of both sexes 2) BMI less than 30 kg per square meter 3) Patient with grade 2 and 3 non-alcoholic fatty liver disease, which is diagnosed by ultrasound. Exclusion criteria: Having special diets Pregnancy and lactation during the study Viral hepatitis

Intervention groups

The intervention group will be advised to consume at least 4 serving of fruit per day and the control group will be advised to consume no more than 2 serving of fruit per day.

Main outcome variables

Determination of the effect of fruit rich diet on hepatic steatosis, liver enzymes, insulin resistance, lipid profile and anthropometric indices in patients with non-alcoholic fatty liver disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048982N1**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date

2020-10-15, 1399/07/24

Registrant information

Name

Farkhondeh Alami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of fruit rich diet on liver steatosis, liver enzymes, insulin resistance, lipid profile, and anthropometric measurements in patient with non alcoholic fatty liver disease

Public title
Effect of fruit rich diet in patient with non alcoholic fatty liver disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
BMI less than 30 kg per square meter Patient with grade 2 and 3 non-alcoholic fatty liver disease, which is diagnosed by ultrasound
Exclusion criteria:
Having special diets Pregnancy and lactation during the study Viral hepatitis Alcohol consumption Diabetes mellitus Psychopathy Failure to follow the fruit consumption according to our recommendations during the study Untreated hypothyroidism Kidney disease Taking medications that can increase GGT levels Heart failure and bone disease Deficiency of alpha-1 antitrypsin Digestive diseases Smoking Menopause
Age
From **19 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
After controlling the inclusion and exclusion criteria, participants will be randomly assigned and matched in two groups based on non-alcoholic fatty liver grade, age and sex by using the Stratified Block Randomization program.
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
Urmia university of medical sciences
Street address
Resalat Street, Emergency Alley
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2020-03-02, 1398/12/12
Ethics committee reference number
IR.UMSU.REC.1398.535

Health conditions studied

1

Description of health condition studied
Non- alcoholic fatty liver disease
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hepatic steatosis, liver enzymes, insulin resistance, lipid profile and anthropometric indices
Timepoint
6 months
Method of measurement
Biochemical measurements, ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group, along with the usual treatment, will be recommended to consume at least 4 serving of fruit per day.
Category
Lifestyle

2

Description
Control group: In addition to the usual treatment, it will be recommended that their daily fruit consumption should not exceed 2 serving.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Dr. Kamran Shateri

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Ayatollah Modarres Blvd., Ershad St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Urmia 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
Oroumia University of Medical Sciences

Full name of responsible person
Farkhondeh Alami

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Preservation of patient information
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available