

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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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Email address

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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

Oroumia University of Medical Sciences

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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