Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

Evaluation the effect of meal pattern on hepatic fibrosis, steatosis, and enzymes, lipid profile, and anthropometric measurements in patient with non alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effect of meal pattern on fibrosis, steatosis and liver enzymes, lipid profile, and anthropometric indices in patients with non-alcoholic fatty liver

Design
A controlled randomized clinical trial with a parallel group design of 112 patients

Settings and conduct
The present study is a parallel controlled randomized clinical trial for 3 months with the aim of investigating the pattern of meals on fibrosis, steatosis and liver enzymes, lipid profile and anthropometric indices in patients with NAFLD referred to the gastrointestinal clinic in Imam Khomeini Hospital will be performed in Urmia.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non-alchoholic fatty liver disease patients older than 18 years of both sexes. Exclusion criteria: Having special diets, Pregnancy and lactation during the study, Viral hepatitis and ascites, Alcohol consumption ,Diabetes mellitus

Intervention groups
The first group: it will be recommended to skip their breakfast and during the day, in addition to lunch and dinner, receive two snacks in the evening and at the end of the night.The second group: they will be advised to skip their dinner and during the day, in addition to breakfast and lunch, they will receive two snacks and their last daily meal will be in the evening.Group 3: It will be recommended to receive only three main meals (breakfast, lunch and dinner) during the day. Fourth or control group: In addition to the three main meals, it will be recommended to have three snacks.

Main outcome variables
steatosis and liver fibrosis, mean serum concentrations of liver enzymes including ALT, AST, ALP and GGT, mean serum concentrations of lipid and lipoprotein profiles including HDL-c, LDL-c, total cholesterol and triglycerides.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201010048982N2**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date
2021-08-22, 1400/05/31

Registrant information

Name
Farkhondeh Alami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3333 7906

Email address
far.alami28@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-20, 1400/03/30

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of meal pattern on hepatic fibrosis, steatosis, and enzymes, lipid profile, and anthropometric measurements in patient with non alcoholic fatty liver disease

Public title

Evaluation the effect of meal pattern on Non alcoholic fatty liver disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

older than 18 years of both sexes Non-alcoholic fatty liver disease diagnosed by FibroScan. Non-alcoholic fatty liver disease

Exclusion criteria:

Having special diets Viral hepatitis and ascites Alcohol consumption Diabetes mellitus kidney Diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples will be randomly divided into intervention and control groups. The intervention groups will be given codes A, B, C and the control group will receive code D. The study blocking is as follows: All block modes of these 4 groups are 24 numbers: ABCD, ABDC, ACDB, ACBD, ADBC, ADCB, BACD, BADC, BCAD, BCDA, BDAC, BDCA, CABD, CADB, CBAD, CBDA , CDAB, CDBA, DABC, DASB, DBCA, DBAC, DCAB, DCBA. These blocks will be placed in sealed envelopes inside a container. Then they will be drawn one by one, the first block to be removed will be selected as the first block. In fact, this will be repeated 28 times to complete the sample size. In this way, people enter the study and thus will be divided into groups.

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

Ethnic committee of Urmia University of Medical Sciences

Street address

Hashteshahrivar street

City

Urmia

Province

West Azarbaijan

Postal code

5614687911

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

IR.UMSU.REC.1399.350

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

Fibrosis

Timepoint

At the beginning and end of the study (beginning and end of 3 months)

Method of measurement

FibroScan

2

Description

Liver enzymes

Timepoint

At the beginning and end of the study (beginning and end of 3 months)

Method of measurement

At the beginning and end of the study, 5 cc of venous blood sample will be taken after 12 hours of fasting

3

Description

Steatosis

Timepoint

At the beginning and end of the study (beginning and end of 3 months)

Method of measurement
At the beginning and end of the study, 5 cc of venous blood sample will be taken after 12 hours of fasting

4

Description
Lipid profile
Timepoint
At the beginning and end of the study (beginning and end of 3 months)
Method of measurement
At the beginning and end of the study, 5 cc of venous blood sample will be taken after 12 hours of fasting

5

Description
Anthropometric measurements
Timepoint
At the beginning and end of the study (beginning and end of 3 months)
Method of measurement
At the beginning and end of the study, 5 cc of venous blood sample will be taken after 12 hours of fasting

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: It will be recommended to eliminate their breakfast and during the day, in addition to lunch and dinner, receive two snacks in the evening and at the end of the night.
Category
Lifestyle

2

Description
Intervention group 2: They will be advised to skip dinner and have two snacks during the day in addition to breakfast and lunch, and their last daily meal will be in the evening.
Category
Lifestyle

3

Description
Intervention group 3: It will be recommended to eat only three main meals (breakfast, lunch and dinner) during the day.
Category
Lifestyle

4

Description
Control group: It will be recommended to have three main meals (breakfast, lunch and dinner) and three snacks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital in Urmia
Full name of responsible person
Dr. Mohammad Alizadeh
Street address
Hashte shahrivar street
City
Urmia
Province
West Azarbaijan
Postal code
5614687911
Phone
+98 45 3333 7906
Fax
+98 45 3333 7906
Email
far.alami28@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Mohammad Alizadeh
Street address
Hashte shahrivar street
City
Urmia
Province
West Azarbaijan
Postal code
5614687911
Phone
+98 45 3333 7906
Fax
+98 45 3333 7906
Email
far.alami28@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Oroumia 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
Dr.Mohammad Alizadeh

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Nazloo

City
Urmia

Province
West Azarbaijan

Postal code
5614687911

Phone
+98 45 3333 7906

Fax
+98 45 3333 7906

Email
far.alami28@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr.Mohammad Alizadeh

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Hashte shahrivar street

City
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Province
West Azarbaijan

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5614687911

Phone
+98 45 3333 7906

Fax
+98 45 3333 7906

Email
Far.alami28@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr.Mohammad Alizadeh

Position
Associate Professor

Latest degree
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Other areas of specialty/work
Nutrition

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Hashte shahrivar street

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Province
West Azarbaijan

Postal code
5614687911

Phone
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Fax
+98 45 3333 7906

Email
far.alami28@gmail.com

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable