Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of a diet enriched with whole grains or bran-contained cereals on liver echogenicity, liver function markers, anthropometry, insulin resistance, blood pressure and lipid profile in patients with nonalcoholic fatty liver disease

Protocol summary

Study aim

Determination of the effect of whole or whole grains rich in diet on liver eczhnicity, liver function indexes, anthropometric measurements, insulin resistance, blood pressure and lipid profile in patients with non-alcoholic fatty liver

Design

This study will be conducted as a randomized, parallel controlled clinical trial on 114 patients with non-autochthonous liver.

Settings and conduct

This study is a randomized controlled clinical trial of patients with non-alcoholic fatty liver, who will be referred for 12 weeks.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: The age range is greater than 18 years of age in both sexes and non-alcoholic fatty liver disease detected by ultrasound. Non-compliance criteria include alcohol consumption or history. Positive serology-hepatitis A-B-C. Pregnancy and lactation during the study. Diabetes. Hypothyroidism. Psychopathy. Kidney disease. People who regularly eat at least half the daily cereal intake from whole grains. A major change in lifestyle

Intervention groups

The intervention group includes a list of whole grains including dark breads, brown rice, whole grains, whole grains and whole wheat, legumes like chickpeas, beans, cottage cheese, lentils, whole grains and whole grains, and they are asked to For a period of 12 weeks, add at least half the daily cereal to whole or whole grains.

Main outcome variables

Anthropometric Indices Lipid profile blood pressure Insulin resistance Liver steatosis Glycemic indexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170206032417N3**
Registration date: **2017-12-27, 1396/10/06**
Registration timing: **retrospective**

Last update: **2017-12-27, 1396/10/06**
Update count: **0**

Registration date

2017-12-27, 1396/10/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-24, 1396/04/03

Expected recruitment end date

2017-10-17, 1396/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of a diet enriched with whole grains or bran-contained cereals on liver echogenicity, liver function markers, anthropometry, insulin resistance, blood pressure and lipid profile in patients with nonalcoholic fatty liver disease

Public title
Effect of Whole Grain Diet on Non-Alcoholic Fatty Liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range over 18 years old in both sexes Non-alcoholic fatty liver disease detected by ultrasound
Exclusion criteria:
Alcohol consumption or history Positive serology-hepatitis A-B-C Pregnancy and lactation during the study Diabetes Hypothyroidism Psychopathy kidney Diseases People who regularly receive at least half the daily cereals they consume from whole grains A major change in lifestyle
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Parallel controlled randomized
Blinding (investigator's opinion)
Single blinded
Blinding description
In this one-sided study, only participants are unaware of the allocation of study groups.
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
Urmia University of Medical Sciences,orjans valley, Resalat boulevard
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5714783734
Approval date
2016-10-26, 1395/08/05
Ethics committee reference number
umsu.rec.1395.300

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Weight
Timepoint
At weeks 0,12
Method of measurement
Scale, kg

2

Description
Triglyceride
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg\dl

3

Description
Total cholesterol
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method, mg\dl

4

Description
LDL cholesterol
Timepoint
At weeks 0 ,12
Method of measurement
(LDL= Total cholestrol – (HDL+ TG/5))

5

Description
HDL cholesterol
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method, mg\dl

6

Description
Fasting blood sugar
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method, mg\dl

7

Description
Serum insulin
Timepoint
At weeks 0,12
Method of measurement
Radioimmunoassay

8

Description
Alanine Aminotransferase
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method, IU\ Lit

9

Description
Aspartat transaminase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU\ Lit

10

Description
Gamma Glutamyl transferase
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method , IU\ Lit

11

Description
Hepatic steatosis
Timepoint
Before intervention and three months intervention
Method of measurement
Ultrasonography

12

Description
Systolic blood pressure
Timepoint
At weeks 0 ,12
Method of measurement
Mercury sphygmomanometer, mmhg

13

Description
Diastolic blood pressure
Timepoint
At weeks 0, 12
Method of measurement
Mercury sphygmomanometer, mmhg

14

Description
Height
Timepoint
Before intervention
Method of measurement
Stadiometer, mm

15

Description
Body mass index
Timepoint
At weeks 0 ,12
Method of measurement
Weight(kg)\[height(m)]2 , kg\m2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, people in the intervention group after become aware of foods that are considered as whole grains,for 3 months will change their daily intake of cereals from refined grain to whole grains or grains with bran. in order to provide at least four serving of whole grains, And they will be asked to not change their physical activity during this time.
Category
Treatment - Other

2

Description
Control group: In this study, individuals in the control group were asked to take their usual daily intake of cereals for 3 months and not to change their physical activity.
Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghods clinic
Full name of responsible person
Dr. Ali jafari heydarlu
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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?
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
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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
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