

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 echogenicity, 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

Name

Mohammad Alizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 2375

Email address

alizadeh.m@umsu.ac.ir

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

City

Urmia

Province

West Azarbaijan

Postal code

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 cholesterol - (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

$\text{Weight(kg)} / [\text{height(m)}]^2$, 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

Street address

West Azerbaijan Province, Urmia, N Khayam St

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 7601

Fax

+98 44 3222 0341

Email

masoomeh.dorosti@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

alizadeh.m@umsu.ac.ir

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

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 2375

Fax

+98 44 3278 0801

Email

alizadeh.m@umsu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 2375

Fax

+98 44 3278 0801

Email

alizadeh.m@umsu.ac.ir

Phone

+98 44 3275 2375

Fax

+98 44 3278 0801

Email

masoomeh.dorosti@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Masoomeh Dorosti

Position

MS student of nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

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