

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of replacing lunch grains with quinoa in the diet on anthropometric indicators, blood lipid composition, glycemic status, inflammatory markers, steatosis and liver fibrosis in patients with NAFLD.

Protocol summary

Study aim

Investigating the effect of replacing cereal for lunch with quinoa in the diet on anthropometric indicators, blood lipid composition, glycemic status, inflammatory markers and steatosis and liver fibrosis in patients with non-alcoholic fatty liver disease.

Design

A clinical trial with a control group, with parallel groups, without blinding (open label), randomized, on 42 patients. Randomization by Balanced Block Randomization method. Excel software is used for randomization.

Settings and conduct

Out of 42 patients referred to medical centers who have the conditions to enter the study were included. After receiving consent, people are randomly divided into two control and intervention groups. At the beginning and end of the study, the desired questionnaires and blood samples will be received.

Participants/Inclusion and exclusion criteria

Entry conditions: age between 18 and 50 years, with evidence of non-alcoholic steatohepatitis with a Controlled Attenuation Parameter score above 263, without chronic inflammatory disease; body mass index above 25 to 29.9. Conditions of non-entry: history of cancer, kidney disease, diabetes, cardiovascular diseases and digestive disorders affecting absorption, weight loss of more than 8% in the last 6 months and use of weight loss drugs, history of allergy to quinoa, pregnancy, breastfeeding and Menopause in women, history of drug and alcohol use and hepatotoxic drugs

Intervention groups

The intervention group receives quinoa seeds as a grain for lunch and weight loss diet. The control group receives the weight loss diet.

Main outcome variables

Alanine transaminase, Aspartate aminotransferase, and

Gamma-glutamyl transferase 'Hepatic steatosis and fibrosis' Lipid profile and index of insulin resistance and sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N37**

Registration date: **2023-03-23, 1402/01/03**

Registration timing: **prospective**

Last update: **2023-03-23, 1402/01/03**

Update count: **0**

Registration date

2023-03-23, 1402/01/03

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of replacing lunch grains with quinoa in the diet on anthropometric indicators, blood lipid composition, glycemic status, inflammatory markers, steatosis and liver fibrosis in patients with NAFLD.

Public title

The effect of replacing lunch grains with quinoa in the diet in patients with NAFLD.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with non-alcoholic steatohepatitis and Controlled Attenuation Parameter score more than 263 No history of alcohol abuse Absence of other diseases and chronic and acute liver disorders Absence of pregnancy, breastfeeding and menopause in women Not taking hepatotoxic drugs such as phenytoin, amoxifen and lithium Not having lost more than 8 percent weight in the last 6 months Blood pressure less than 140/90 mmHg No kidney disease Not using weight loss drugs No history of allergy to quinoa No history of cardiovascular diseases, diabetes and gastrointestinal disorders affecting absorption Absence of pituitary, thyroid disorders Willingness to participate in the study Not having clinically diagnosed psychiatric disorders that impair the patient's ability to provide written informed consent

Exclusion criteria:

Taking medicine or supplements that can affect the results Failure to accept study conditions pregnancy

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **42****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization in this study will be random and by Balanced Block Randomization method. The random sequence list will be designed and used by Excel software. Based on this list, the researcher places people in the intervention or control group.

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**

Ethics Committee of National Nutrition and Food Technology Research Institute (NNFTRI)

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#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb

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Postal code

1981619573

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1401.056

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**

Level of steatosis and liver fibrosis

Timepoint

At the beginning and 3 months after the start of the study

Method of measurement

Fibroscan

Secondary outcomes**1****Description**

lipid profil

Timepoint

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

Method of measurement

blood sample

2**Description**

insulin sensitivity index

Timepoint

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

Method of measurement

math formula

3**Description**

Insulin resistance index

Timepoint

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

Method of measurement

math formula

4**Description**

Insulin concentration

Timepoint

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

Method of measurement

blood sample

5**Description**

Anthropometric indices

Timepoint

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

Method of measurement

Tape measure, scale and mathematical formula

6**Description**

blood pressure

Timepoint

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

Method of measurement

Sphygmomanometer

7**Description**

high-sensitivity C-reactive protein

Timepoint

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

Method of measurement

blood sample

8**Description**

Liver enzymes alanine transaminase, aspartate aminotransferase, gamma-glutamyl transferase

Timepoint

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

Method of measurement

blood sample

Intervention groups**1****Description**

Intervention group: consumption of quinoa seeds for lunch instead of other grains and weight loss diet for 3 months. The amount of quinoa consumed for each person will be calculated based on the amount of energy needed by the person. A 24-hour feed record will be received for 3 days at the beginning and end of the study, including one holiday and two non-holiday days. Domestically grown white quinoa will be used.

Category

N/A

2**Description**

Control group: weight loss diet for 3 months and receive weight loss diet

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Payambaran hospital

Full name of responsible person

Parvin Mirimiran

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Payambaran Hospital, Abazar Blvd. Ayat Allah kashani Blv, Sadeqieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvin Mirmiran

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taghzieh_uni@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsane GHolamrezayi

Position

student

Latest degree

Master

Other areas of specialty/work

Nutrition

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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