Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 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 tansferase ؛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
Age
From **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)
Street address
#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb
City
Tehran
Province
Tehran
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 tansferase
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
Street address
Payambaran Hospital,Abazar Blvd.Ayat Allah kashani Blv, Sadeqieh
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1471754994
Phone
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Email
info@payambaranhospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parvin Mirmiran

Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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1981619573

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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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Latest degree
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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