

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of ketogenic diet on patients with fatty liver

Protocol summary

Study aim

Investigating the effect of ketogenic diet on fatty liver

Design

A clinical trial with a control group, parallel groups, without blinding, randomized, on 60 patients, randomization blocks were performed with random allocation software.

Settings and conduct

The study is conducted on 60 patients with fatty liver who were referred to the gastroenterology clinic of the Velayat hospital. Patients will be divided into two groups receiving a common diet and a ketogenic diet. The level of liver enzymes and ultrasound findings are checked at the beginning and 3 months after the start of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Non-alcoholic fatty liver disease; Body mass index of more than 25 kg/m²; Patient age between 20 and 60 years; Not receiving the diet and exercise program in the past year; Exclusion criteria: Suffering from chronic kidney diseases, heart diseases, and other liver; diseases (hepatitis, liver cirrhosis), diabetic patients treated with insulin; Pregnancy or breastfeeding among female participants; Unwillingness to participate in the study;

Intervention groups

Control group: common diet (a low-calorie diet that is high in carbohydrates (55%–60% of total daily energy intake) for 3 months. Intervention group: Ketogenic diet (a high-fat, adequate-protein, low-carbohydrate diet (less than 20%). In this diet, foods containing meat, cheese, cream, healthy oils, nuts, and seeds, etc., are consumed instead of foods containing sugar, grains and starches, fruits except berries, beans and legumes, alcohol, etc.) for 3 months.

Main outcome variables

Level of alanine aminotransferase, aspartate transaminase, low and high density lipoprotein, triglycerides, bilirubin in blood and degree of fatty liver in ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220814055693N1**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

mehran ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

nafas.20.rastgoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-31, 1401/06/09

Expected recruitment end date

2023-08-31, 1402/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ketogenic diet on patients with

fatty liver

Public title

Effect of ketogenic diet on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Non-alcoholic fatty liver diseases
Body mass index more than 25 kg/m²
Patient age between 20 and 60 years
Not receiving the diet and exercise program in the past year

Exclusion criteria:

Suffering from chronic kidney diseases, heart diseases and other liver diseases (hepatitis, liver cirrhosis), diabetic patients treated with insulin
Pregnancy or breastfeeding among female participants
Unwillingness to participate in the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be individually divided into two groups a (ketogenic diet) and b (common diet) using the random block method. The size of each block is 4. The random allocation tool is random allocation software.

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 Qazvin University of Medical Sciences

Street address

Research and Technology deputy, Mavaddat Alley, Shahid Beheshti Blvd, Qazvin Town

City

Qazvin

Province

Qazvin

Postal code

3471976161

Approval date

2021-01-20, 1399/11/01

Ethics committee reference number

IR.QUMS.REC.1399.415

Health conditions studied

1

Description of health condition studied

Ketogenic diet

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified, Nonalcoholic fatty liver disease [NAFLD]

Primary outcomes

1

Description

Alanine transaminase

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood test, Hitachi 912 biochemical machine

2

Description

Aspartate aminotransferase

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood test, Hitachi 912 biochemical machine

3

Description

low-density lipoprotein

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood test, Hitachi 912 biochemical machine

4

Description

High-density lipoprotein

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood test, Hitachi 912 biochemical machine

5

Description

Triglycerides

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood test, Hitachi 912 biochemical machine

6

Description

Blood Bilirubin

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Laboratory sample, Malloy_elys method

7

Description

Fatty liver grade

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Control group: A common diet (a low-calorie diet with moderate carbohydrates in which the share of carbohydrates is 55% of the total energy) is provided to the patients for 3 months. In the first session, under the supervision of the researcher, daily meals are given to the patient for a whole week and The method of food consumption is explained, then the other diet is provided to the patients by telephone or in person. If the patients need to change the diet or cause problems in its implementation, the researcher is informed.

Category

Treatment - Other

2

Description

Intervention group: Ketogenic diet (a high-fat, adequate-protein, low-carbohydrate diet(less than 20%). In this diet, foods containing meat, cheese, cream, healthy oils, nuts, and seeds, etc., are consumed instead of foods containing sugar, grains and starches, fruits except berries, beans and legumes, alcohol, etc..) for 3 months. In the first session, under the supervision of the researcher, daily meals are given to the patient for a

whole week and the method of food consumption will be explained, then the other diet will be provided to the patients by phone or in person by the researcher. If the patients need to change their diet or cause problems in its implementation, the researcher will be informed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vellayat Hospital

Full name of responsible person

Mehran Ebrahimi

Street address

Vellayat hospital, 22 Bahman boulevard, Elahieh alley, Minoodar town, Qazvin

City

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Postal code

3471976161

Phone

+98 28 3379 0620

Email

Clinical_research@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mirhashemi

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran

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Qazvin

Province

Qazvin

Postal code

3415613911

Phone

+98 28 3333 7006

Email

researchdpt@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Mehran Ebrahimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Velayat hospital,22 Bahman boulevard,Elahieh alley,
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Phone

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Fax**Email**

Mehraneb.3046@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Mehran Ebrahimi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Mehran Ebrahimi

Position

Resident

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Fax**Email**

Mehraneb.3046@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after individuals are de-identified

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

The data will be available to researchers working in
academic and scientific institutions

Under which criteria data/document could be used

Any kind of analysis on the delivered data is allowed

From where data/document is obtainable

Refer to Dr. Ebrahimi's email

What processes are involved for a request to access

data/document

After publication of the article, the applicant is able to

access the information by sending an email to the author

Comments