Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 transamylase, 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
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Iran (Islamic Republic of)
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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_evelyn 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
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Vellayat hospital, 22 Bahman boulevard, Elahieh alley, Minoodar town, Qazvin
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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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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
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Person responsible for updating data

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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