

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of kefir drink on hepatic enzymes, lipid profiles, glycemic indices, inflammation, oxidative stress, anthropometric factors and blood pressure in patients with non-alcoholic fatty liver disease.

Protocol summary

Study aim

the aim of this study were to evaluate the effects of kefir drinks on non-alcoholic fatty liver disease.

Design

randomised, parallel group trial with with control and intervention group

Settings and conduct

select non-alcoholic fatty liver patients based on inclusion and exclusion criteria that referred to Motahhari clinic. then completed consent and other questionnaires for participants. finally patients settled on either groups based on randomisation. Patients will not be aware of the two groups being studied.

Participants/Inclusion and exclusion criteria

inclusion criteria: age 18 to 65 years, body mass index more than 25, ALT more than 19 and 30 for males and women respectively,... exclusion criteria: presence of another type of liver disease, kidney, cardiovascular and thyroid disease, weight loss more than 3 kg within previous 3 month, using alcohol and ...

Intervention groups

control group: receive balanced diet which 500 Kilo calorie lower than estimated energy requirements.
intervention group: receive balanced diet + 2 glasses kefir drink daily for 8 weeks.

Main outcome variables

alteration hepatic enzymes, weight, lipid profiles, blood pressure, inflammation and oxidative stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170916036204N6**

Registration date: **2018-08-03, 1397/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Najmeh Hejazi

Name of organization / entity

Shiraz University of Medical Sciences, Faculty of Nutrition and Food Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1005

Email address

nhejazi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of kefir drink on hepatic enzymes, lipid profiles, glycemic indices, inflammation, oxidative stress, anthropometric factors and blood pressure in patients with non-alcoholic fatty liver disease.

Public title

The effect of kefir drink on non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
grade 1,2 & 3 fatty liver, new fatty liver diagnosed patients, and fatty liver confirmed by physician. Alt>30 in males and ALT>19 in females. age: 18-65 BMI>25 controlled Diabetes and lipid profile.
Exclusion criteria:
presence of another type of liver disease, cirrhosis, hepatitis B and C, cardiovascular and kidney disease, autoimmune, hypothyroidism, wilson, cystic fibrosis, Deficiency of alpha-1-antitrypsin 1, inflammatory bowel disease and hemochromatosis. using alcohol taking nutritional and probiotic supplements within the previous 6 weeks. having weight loss more than 3 Kg within 3 month ago participating in other trials in the last 6 month being pregnant or breast feeding do not want to participate in this trial.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization, individual, Random allocation software, 20 randomization sequence in permuted blocks of size four

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 Shiraz University of Medical Sciences

Street address

Zand street, Before Namazi square, Central department of Shiraz University of Medical Sciences.

City

Shiraz
Province
Fars
Postal code
7153675541

Approval date

2018-04-08, 1397/01/19

Ethics committee reference number

IR.sums.REC.1397.107

Health conditions studied

1

Description of health condition studied

non-alcoholic fatty liver disease

ICD-10 code

k77

ICD-10 code description

non-alcoholic, fatty liver disease

Primary outcomes

1

Description

Alanine aminotransferase

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

ALT kit

2

Description

Aspartate transaminase

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

AST kit

3

Description

weight

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

seca scale

Secondary outcomes

1

Description

blood pressure

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Mercury barometric device

Intervention groups

1

Description

Intervention group:received diet therapy + kefir drink 2 glasses(500 ml) every day for 8 weeks. Kefir will be purchased from Pegah Fars Factory.

Category

Treatment - Devices

2

Description

Control group: received diet that 500 kilo calorie less than energy requirements for 8 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari clinic

Full name of responsible person

Najmeh Hejazi

Street address

Shiraz University of Medical Sciences, Namazi square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor seyed Basir hashemi

Street address

shiraz university of medical sciences-vice chancellor for research affairs Shiraz

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nadia Razmjooei

Position

Master of science in Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Najmeh Hejazi

Position

PHD in nutrition sciences, assistant professor of nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

Shiraz University of Medical Sciences

Full name of responsible person

Nadia Razmjooei

Position

master of nutrition sciences

Latest degree

Master

Other areas of specialty/work

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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