

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effects of probiotic yogurt fortified with vitamin D in comparison to conventional yogurt on hepatic enzymes, lipid profile, glycemic and anthropometric indices in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

1- Comparison of changes in liver enzymes (ALT, AST) before and after consumption of vitamin D fortified probiotic yogurt or simple yogurt in patients with non-alcoholic fatty liver disease 2- Comparison of changes in lipid profile (HDL, LDL, Tchol, TG) before and after consumption of vitamin D fortified probiotic yogurt or simple yogurt in patients with non-alcoholic fatty liver disease 3- Comparison of changes in glycemic indexes (Insulin and FBS) before and after consumption of vitamin D fortified probiotic yogurt or simple yogurt in patients with non-alcoholic fatty liver disease 4- Comparison of changes in anthropometric indices (weight, abdomen circumference, hip circumference, abdomen to hip ratio) before and after consumption of vitamin D fortified probiotic yogurt or simple yogurt in patients with non-alcoholic fatty liver disease

Design

In this research, 90 patients with grade 1 or 2 fatty liver, who are eligible to enter the study, referred from the ultrasound clinic, are selected. The participants will be randomly assigned to two 45-member groups including the control group (receiving conventional yogurt 100 gr per day) and the intervention group (receiving probiotic yogurt enriched with vitamin D, 100 gr per day). Randomization will be done using the random numbers table and will receive the relevant code. This trial is a double blind randomized clinical trial.

Settings and conduct

This study will be conducted at Kermanshah Nutrition and food Sciences Faculty. Individuals will complete consent form, demographic information and physical activity questionnaire. The weight, height, and body composition are determined using the body analyzer. The fasting blood sample will also be taken about 10 cc. In this study the factory will use two different codes for 2 kinds of yogurt instead of their names to make blinding

possible. Therefore the patients, the main presenter, the data collectors, the yogurt distributors, as well as the persons who analysis the data, will be blind from the beginning to the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: individuals with new diagnosed fatty liver disease; individuals with grade 1 or 2 fatty liver disease; individuals with the age of 25 to 55 years old; individuals who are completely content. Non-inclusion criteria: individuals who use any kind of medication; individuals who are allergic to yogurt; individuals who are suffering from other chronic diseases like cardiovascular diseases, kidney diseases, thyroid diseases, any kind of hepatitis, cirrhosis or had liver transplant; individuals who had a background of cancer; women who use contraceptive drugs; individuals who use certain regimens or weight loss regimens; individuals who use any vitamin supplements; individuals who use any kind of probiotic supplement or probiotic food products; individuals who take any antioxidant supplements; individuals who have taken any type of fiber containing supplement or omega 3 supplement during 6 weeks before starting the study; individuals who have taken antibiotics over the 2 weeks before starting the study; pregnancy; breast feeding; menopause; cigarette smoking; alcohol use

Intervention groups

The control group includes people who will receive simple yogurt and in the intervention group, the participants will receive yogurt with vitamin D and probiotics.

Main outcome variables

Changes in liver enzymes; lipid profile; glycemic and anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131022015111N3**

Registration date: **2018-02-18, 1396/11/29**

Registration timing: **retrospective**

Last update: **2018-02-18, 1396/11/29**

Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

Name

Seyyed Mostafa Nachvak

Name of organization / entity

kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1826 2005

Email address

m.nachrak@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of probiotic yogurt fortified with vitamin D in comparison to conventional yogurt on hepatic enzymes, lipid profile, glycemic and anthropometric indices in patients with non-alcoholic fatty liver disease

Public title

Effect of probiotic yogurt fortified with vitamin D on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

individuals with new diagnosed fatty liver disease

individuals with grade 1 or 2 fatty liver disease

individuals with the age of 25 to 55 years old individuals

who have full satisfaction to participate

Exclusion criteria:

individuals who use any kind of drug individuals who has allergic to yogurt individuals who are suffering from other chronic diseases like: cardio vascular diseases,

kidney diseases, thyroid and... individuals who are

suffering from other chronic diseases like: any kind of

hepatitis, cirrhosis and ... or had liver transplant.

individuals who had a background of cancer women who

use contraceptive drugs individuals who use certain

regimens or weight loss regimens. individuals who use any vitamin supplements individuals who use any kind of probiotic supplement or probiotic food products individuals who take any antioxidant supplements individuals who have taken any type of fiber supplement or omega-3 supplement during 6 weeks before starting the study. individuals who have taken antibiotics over the 2 weeks before starting the study. Women who are pregnant, lactating or menopause. individuals who use cigarettes and alcohol.

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual Randomization - Using Random Number Tables

Blinding (investigator's opinion)

Triple blinded

Blinding description

- The appearance of yogurt is the same for both participants in both groups. - Ultrasound specialist will not be aware of the group of individuals. - The main investigator will not be aware of the content of yogurts and also of the group which they are in. - The staff of collecting information, the yogurt providers and also description providers will also be unaware of the content of yogurt and the group of participants. - persons who analyzing data will be unaware of the kind of group which each person belong.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee, Building No 2 of Kermanshah
University of Medical Sciences, Naft Square, Shahid
Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2018-01-03, 1396/10/13

Ethics committee reference number

IR.KUMS.REC.1396.536

Health conditions studied**1****Description of health condition studied**

fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Alanine Aminotransferase

Timepoint

Before and 3 month after intervention

Method of measurement

by using Kit

2**Description**

Aspartate Aminotransferase

Timepoint

Before and 3 month after intervention

Method of measurement

by using Kit

3**Description**

Total Cholesterol

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

4**Description**

Triglyceride

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

5**Description**

Low-density lipoprotein

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

6**Description**

High-density lipoprotein

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

7**Description**

Fast Blood Sugar

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

8**Description**

Serum Insulin

Timepoint

Before and 3 month after intervention

Method of measurement

Insulin MONOBIND Kit

9**Description**

Weight

Timepoint

Before and 3 month after intervention

Method of measurement

scale

10**Description**

Abdomen Circumference

Timepoint

Before and 3 month after intervention

Method of measurement

Tape measure

11**Description**

Hip Circumference

Timepoint

Before and 3 month after intervention

Method of measurement

Tape measure

12

Description

Body Fat Percentage

Timepoint

Before and 3 month after intervention

Method of measurement

Body Analyzer Machine

13

Description

Body Muscle Percentage

Timepoint

Before and 3 month after intervention

Method of measurement

Body Analyzer Machine

14

Description

vitamin D

Timepoint

Before and 3 month after intervention

Method of measurement

By using Kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Riched yogurt (100 cc/day) with 1000 IU vitamin D and 40000000 cfu Probiotic

Category

Treatment - Other

2

Description

Control group: Plain yogurt (100 cc/day) receiving group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Javad Orfi

Street address

Imam Reza Hospital, Zakariya Razi Blvd, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3723 3221

Email

morvaridzadehm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Kurosh Hamzei

Street address

Vice Chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3837 6895

Email

morvaridzadehm@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mojgan Morvaridzadeh

Position

MSC Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Nutrition and Food Sciences Faculty, Next to the
Farabi Hospital, Dolat Abad Blvd, Isar Square, Imam
Hosein Exp,

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3723 3221

Email

morvaridzadehm@yahoo.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Seyed Mostafa Nachvak

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition and Food Sciences Faculty, Next to the
Farabi Hospital, Dolat Abad Blvd, Isar Square, Imam
Hosein Exp,

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83388264165

Email

Smnachvak@hotmail.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Mojgan Morvaridzadeh

Position

MSC Student

Latest degree

Bachelor

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Kermanshah

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Phone

+98 83 3723 3221

Email

morvaridzadehm@yahoo.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Trials that began to sample collection on January 11,
2018 should have a release plan when registering their
study protocol

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available