Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 cardio vascular 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

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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
Trigliceride
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
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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.
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Phone
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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

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Latest degree
Bachelor
Other areas of specialty/work
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Province
Kermanshah
Postal code
6719851351
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