Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of probiotics on changes in liver enzymes, lipid factors and ultrasound evidence in children and adolescents aged 10 to 18 years with non-alcoholic fatty liver

Protocol summary

Study aim

Determining the effect of probiotics on body mass index, fasting serum sugar, lipid factors (triglyceride level, total cholesterol, LDL, HDL), liver enzymes (AST and ALT) and ultrasound evidence of liver in children and adolescents 10 to 18 years with disease Non-alcoholic fatty liver

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, randomization list through www. sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct

Children and adolescents with non-alcoholic fatty liver disease referred to the clinic of Shahid Beheshti Hospital in Kashan will be randomly divided to receive Familact supplement or placebo for 8 weeks. In order to blind patients, the same drug (in terms of shape, size and color) will be prepared with the main drug. In order to blind the clinical caregiver (physicians or nutritionist), the drugs used for patients will be provided in coded form.

Participants/Inclusion and exclusion criteria

Children and adolescents 10 to 18 years with non-alcoholic fatty liver disease

Intervention groups

Intervention group: Receiving Familact supplement for 8 weeks (Familact 500 mg prepared from Biology fermentation Company, once a day after meals) Control group: receiving placebo for 8 weeks once a day after meals

Main outcome variables

body mass index, fasting serum sugar, lipid factors (triglyceride level, total cholesterol, LDL, HDL), liver enzymes (AST and ALT) and ultrasound evidence of liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220314054279N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **retrospective**

Last update: **2022-07-19, 1401/04/28**
Update count: **1**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

maryam naseri taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

2021-01-20, 1399/11/01

Actual recruitment end date

2021-10-22, 1400/07/30

Trial completion date

2021-12-22, 1400/10/01

Scientific title
The effect of probiotics on changes in liver enzymes, lipid factors and ultrasound evidence in children and adolescents aged 10 to 18 years with non-alcoholic fatty liver

Public title
The effect of probiotics on changes in liver enzymes, lipid factors and ultrasound evidence in children and adolescents aged 10 to 18 years with non-alcoholic fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children and adolescents 10 to 18 years of age with non-alcoholic fatty liver disease confirmed by ultrasound and ALT more than 1.5 to 5 times normal

Exclusion criteria:
Patients with alcoholic steatohepatitis Patients with systemic diseases (such as diabetes), inflammatory diseases, autoimmune diseases of the liver Positive serology of viral hepatitis Positive AMA ANA Positive Ceruloplasmin Children with hypothyroidism Taking nutritional supplements Other secondary causes of fatty liver Patients with any medication that affects the liver Liver enzyme levels are more than 6 times normal

Age
From **10 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 60 (two groups of 30) and permuted block randomization method (block size=4) (15 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (60th person).

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind patients, the same drug (in terms of shape, size and color) will be prepared with the main drug. In order to blind the clinical caregiver (physicians or nutritionist), the drugs used for patients will be provided in coded form.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Qutb Ravandi Boulevard - Kashan University of Medical Sciences

City
kashan

Province
Isfehan

Postal code
8715981151

Approval date
2020-11-11, 1399/08/21

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.144

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
DB92

ICD-10 code description
Non-alcoholic fatty liver disease

Primary outcomes

1

Description
Liver enzymes (ALT,AST)

Timepoint
At the beginning of the study, 8 weeks after taking the drug

Method of measurement
blood test

2

Description
Lipid factors (cholesterol, LDL, HDL)

Timepoint
At the beginning of the study, 8 weeks after taking the drug
Method of measurement
blood test

3

Description
Fatty liver grade
Timepoint
At the beginning of the study, 8 weeks after taking the drug
Method of measurement
Sonography

Secondary outcomes

1

Description
Body mass index
Timepoint
At the beginning of the study, 8 weeks after taking the drug
Method of measurement
Meters to measure height and scales to measure weight

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study, 8 weeks after taking the drug
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Receive 500 mg Familact Capsules (Probiotic + Prebiotic) prepared from Zist Takhmir Company, once a day after meals for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Receive placebo capsule (in the form of Familact drug without existing bacteria) prepared from Zist Takhmir company, once a day after meals for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک بیمارستان شهید بهشتی کاشان
Full name of responsible person
مریم ناصری طاهری
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Qutb Ravandi Boulevard, Shahid Beheshti Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Maryam Naseri Taheri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

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Person responsible for updating data

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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