

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Treatment effects of familact Probiotic in Non Alcoholic Fatty Liver Disease(NAFLD)

Protocol summary

Summary

This study aimed to investigate the effect of Familact probiotic in the treatment of patients with NAFLD, as a clinical trial study. And 90 patients with proven NAFLD by ultrasonography and ALT more than 1.5 to 5 times the normal, BMI between 25 to 29.9 with the written consent referred to the gastroenterology clinic in Vali Asr hospital or private offices to be studied. And weight, blood pressure, BMI, liver function tests, blood glucose, and lipid profiles are analyzed. Both groups will be referred to a dietitian. Then randomly divided into two groups (45 people). The control group will have a daily exercise for at least 30 minutes. And the second group will receive Familact capsule 500 mg once daily after a meal. After eight weeks of starting treatment the above cases, re-evaluated by same person in the same laboratory unit. Information collected will be evaluated and compared. And Familact impact in the treatment of NAFLD and reducing liver enzymes checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112019554N2**

Registration date: **2015-07-12, 1394/04/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-12, 1394/04/21

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.shirinjameshorani@zumc.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment effects of familact Probiotic in Non Alcoholic Fatty Liver Disease(NAFLD)

Public title

Treatment effects of familact Probiotic in Non Alcoholic Fatty Liver Disease(NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with NAFLD on ultrasonography; ALT more than 1.5 to 5 times the normal range; BMI between 25 to 29.9 Exclusion criteria: alcoholic hepatitis; systemic or metabolic or inflammatory disease such as diabetes; viral hepatitis; autoimmune hepatitis; secondary fatty liver disease such as drug induced fatty liver disease

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description**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**

Zanjan University of Medical Sciences

Street address

Medical School, Zanjan University of Medical Sciences, Karmandan street, Zanjan

City

Zanjan

Postal code**Approval date**

2015-05-22, 1394/03/01

Ethics committee reference number

A-12-500-5

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

Nonalcoholic steatohepatitis

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases, Nonalcoholic steatohepatitis [NASH]

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

Blood pressure

Timepoint

at the first and after 8 weeks

Method of measurement

Manometer

2**Description**

body mass index

Timepoint

at the first and after 8 weeks

Method of measurement

Analog scale, Meter

3**Description**

fasting blood glucose

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

4**Description**

total cholesterol

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

5**Description**

LDL

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

6**Description**

HDLI

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

7**Description**

TG

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

8**Description**

AST

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

9**Description**

ALT

Timepoint

at the first and after 8 weeks

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

Daily exercise for at least 30 minutes

Category

Lifestyle

2**Description**

Familact capsule 500 mg once daily after a meal

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Dr.Maryam Jameshorani

Street address

Valiasr Hospital, Valiasr Sq, Zanjan

City

Zanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences, Deputy of Research and Technology, Research Management

Full name of responsible person

Dr. Soghrat Faghihzadeh

Street address

Medical School, Zanjan University of Medical Sciences, Karmandan street, Zanjan

City

Zanjan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan University of Medical Sciences, Deputy of Research and Technology, Research Management

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Maryam Jameshorani

Position

Internist

Other areas of specialty/work**Street address**

Valiasr Hospital, Valiasr Sq, Zanjan

City

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Postal code**Phone**

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Fax**Email**

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

Zanjan University of Medical Sciences

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Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty