

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Effect of probiotic in improving laboratory findings in nonalcoholic fatty liver disease

Protocol summary

Summary

nonalcoholic fatty liver disease (NAFLD) is the most common chronic liver disease in children and adults. There is no effective treatment for this disease. Recently, probiotics are suggested as possible treatment. The aim of current study is to evaluate the efficacy of probiotic Gerilact in NAFLD patients. In this double-blinded randomized clinical trial, 60 patients with NAFLD with inclusion criteria and not having exclusion criteria will be recruited and using random numbers and sealed envelopes will randomly assigned to Gerilact or placebo groups. Patients will receive Gerilact 500 mg or placebo twice a day for 60 days. Inclusion criteria are NAFLD grade II and III, BMI 25-40 kg/m² and over 18 years old. Exclusion criteria will be any systemic or chronic liver disease beside NAFLD, cancer, antibiotic therapy two weeks prior or during to study, complement use, alcohol use and pregnancy. Lipid profile, liver function test and sonography will be evaluated before and at the end of the intervention. In this triple blinded study, the patients, physician and the person responsible to collect data will be blinded to the allocated group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102537007N1**
Registration date: **2017-11-12, 1396/08/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

Zahra Sadeghi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Ardabil University of Medical Sciences

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic in improving laboratory findings in nonalcoholic fatty liver disease

Public title

Effect of probiotic in improving laboratory findings in nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with newly diagnosed fatty liver grade II and III; with no treatment for NAFLD; BMI 25-40 kg/m²; over 18 years old. Exclusion criteria: any gastrointestinal disease; diabetes mellitus; cardiac or kidney failure; thyroid disease; rheumatoid arthritis; chronic liver disease beside NAFLD; cancer; antibiotic

therapy two weeks prior or during study; vitamin, antioxidant, fiber and omega3 complement use 3 weeks prior or during study; pregnancy or breast feeding, OCP use; liver transplantation; alcohol use.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medicine Sciences Ethics committee

Street address

Ardabil University of Medicine Sciences, Daneshgah St.,

City

Ardabil

Postal code

53141-56198

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

IR.ARUMS.REC.1396.109

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Lipid profile

Timepoint

Before and at the end of intervention

Method of measurement

with laboratory examination

2

Description

Liver function tests

Timepoint

Before and at the end of intervention

Method of measurement

with laboratory examination

3

Description

Fatty liver grade

Timepoint

Before and at the end of intervention

Method of measurement

With sonography

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, two Gerilact tablets 500 mg will be administered daily for 60 days

Category

Treatment - Drugs

2

Description

In control group, two placebo tablets will be given daily for 60 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ardabil

Full name of responsible person

Dr. Zahra Sadeghi

Street address

Imam Khomeini Hospital, Ataei Ave.,

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr. Masoud Entezari Asl

Street address

Ardabil University of Medical Sciences, Daneshgah St.,

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ardabil University of Medical Sciences

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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Zahra Sadeghi

Position

Internal medicine resident

Other areas of specialty/work

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Contact

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Other areas of specialty/work

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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