Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 thiis 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

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Zahra Sadeghi
Name of organization / entity
Ardabil University of Medical Scineces
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Recruitment status
Recruitment complete

Funding source
Vice chancellor of Ardabil University of Medical Sciecnes

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.,
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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

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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