

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of probiotics supplementation on blood profile on NAFLD patients

Protocol summary

Summary

Objective: the effect of probiotics on the blood parameters in patients with NAFLD. Inclusion criteria: patients with NAFLD; the age range was 18 to 65 years old. Exclusion criteria: patients with NAFLD that used supplemental probiotics of probiotic foods during last 3 months; also those used tobacco and alcohol; patients with cardiovascular diseases, chronic liver and kidney diseases, Wilson disease, Hemochromatosis; people with low immune system ability (autoimmune) and pregnant or lactating women. Population and sample size: 60 patients with NAFLD among people eligible to participate and referred to Baqiyatallah Research Center for Gastroenterology and Liver Disease. Intervention: these patients were divided to either an intervention group (receiving probiotic capsule) or placebo (receiving placebo) groups. After an overnight fasting, subjects referred for blood drawn. After this stage, blood samples tested. After 8 weeks of experiment, fasting blood samples were tested again. Baseline serum LDL-C, HDL-C, TG and total cholesterol, Fasting glucose, insulin, malondialdehyde, TAC, ALT,AST, TNF-a , and IL-6.

General information

Acronym

NAFLD (Non Alcoholic Fatty Liver Disease)

IRCT registration information

IRCT registration number: **IRCT2012122911920N1**

Registration date: **2013-05-19, 1392/02/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-19, 1392/02/29

Registrant information

Name

Sepideh Abbaszadeh

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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abbaszadehs@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Science

Expected recruitment start date

2013-05-31, 1392/03/10

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics supplementation on blood profile on NAFLD patients

Public title

Effect of probiotics on patients with NAFLD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with NAFLD; the age range was 18 to 65 years old. Exclusion criteria: patients with NAFLD that used supplemental probiotics of probiotic foods during last 3 months; also those used tobacco and alcohol; patients with cardiovascular diseases, chronic liver and kidney diseases, Wilson disease, Hemochromatosis; people with low immune system ability (autoimmune) and pregnant or lactating women.

Age

From **18 years** old to **65 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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Science

Street address

Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-05-06, 1392/02/16

Ethics committee reference number

92/736ع

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty Liver Disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Malodialdehyde (MDA)

Timepoint

Before and after Intervention

Method of measurement

ELISA

2

Description

TAC

Timepoint

Before and after Intervention

Method of measurement

ELISA

3

Description

Serum Insulin Levels

Timepoint

Before and After Intervention

Method of measurement

ELISA

4

Description

IL-6

Timepoint

Before and After Intervention

Method of measurement

ELISA

5

Description

Serum Glucose

Timepoint

Before and after Intervention

Method of measurement

Autoanalyzer

6

Description

Lipid Profile (Tg,Total Chol, LDL-C, HDL-C)

Timepoint

Before and After Intervention

Method of measurement

Autoanalyzer

7

Description

TNF-α

Timepoint

Before and after Intervention

Method of measurement

ELISA

8

Description

oxLDL

Timepoint

Before and after Intervention

Method of measurement

ELISA

9**Description**

ALT

Timepoint

Before and after Intervention

Method of measurement

autoanalyzer

10**Description**

AST

Timepoint

Before and after Intervention

Method of measurement

autoanalyzer

Secondary outcomes

empty

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

Control: Placebo Group receiving capsules once daily, for eight weeks.

Category

Treatment - Drugs

2**Description**

Intervention: patients in the treatment group received probiotic capsules (Lactobacillus, Bifidobacter, Streptococcus) once daily for 8 weeks.

Category

Treatment - Drugs

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

Baqiyatallah University of Medical Sciences

Full name of responsible person

ms Rostami

Street addressn. 178 Shadab Square, Sepahbod Gharani Avenue,
Tehran**City**

Tehran

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

Baqiyatallah University of Medical Science

Full name of responsible person

Dr Gashtasb Aghasinejad

Street addressfinancial Deputy of Baqiyatallah University of Medical
Sciences**City**

Tehran

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

Yes

Title of funding source

Baqiyatallah University of Medical Science

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**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Sepideh Abbaszadeh

Position

Food Safety

Other areas of specialty/work**Street address**Baqiyatallah University of Medical Sciences, Tehran,
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r**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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