Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 monthes; 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 Alchoholic 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
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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 monthes; 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

92/736ح

Health conditions studied

1

Description of health condition studied

Non Alchoholic 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 address
n. 178 Shadab Square, Sepahbod Gharani Avenue, Tehran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Science
Full name of responsible person
Dr Gashtasb Aghasinejad
Street address
financial 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
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Person responsible for scientific inquiries

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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