Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The influence of probiotics and Zinc on the serum levels of liver enzymes and lipid profile in patients with non-alcoholic fatty liver disease

Protocol summary

Summary

The aim of this study is assess the influence of probiotics and Zinc on the serum levels of liver enzymes and lipid profile in patients with non-alcoholic fatty liver disease (NAFLD). This is a randomized, triple blind (blinding for patients, doctors and he who analyzed), controlled with placebo and single central study. In this study, 128 patients with NAFLD are studied.Inclusion criteria were Patients with NAFLD and exclusion criteria were autoimmune hepatitis, viral hepatitis, liver metabolic diseases, age below 18 and etc. Patients were randomly (randomized block design) divided into 4 groups of 32 people.The first group receive two probiotic capsules and two zinc capsules, the second group received two probiotic capsules and two zinc concentrate capsules, the third group received two capsules of probiotic placebo and two zinc capsules, and the fourth group received two probiotic capsules and two zinc plaques placebo capsules daily.The intervention time is 3 months. The serum level of ALT, AST, FBS, TG, Total cholesterol, TG, HDL and CRP, and weight, Waist and BMI are measured before and after the intervention, for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080135408N1**
Registration date: **2017-08-12, 1396/05/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-12, 1396/05/21

Registrant information

Name

Masoumeh Khedri

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The influence of probiotics and Zinc on the serum levels of liver enzymes and lipid profile in patients with non-alcoholic fatty liver disease

Public title

The influence of probiotics and Zinc on the patients with non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with non-alcoholic fatty liver disease Exclusion criteria: autoimmune hepatitis- viral hepatitis- liver metabolic diseases- liver metabolic

disease- drugs and toxins inception- age below 18- History of receiving medication for NAFLD- History of kidney or heart disease- Taking amiodarone, methotrexate, tamoxifen, glucocorticoids, sodium valproate and anti HIV drugs.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **128**

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
Ethics committee of Ahvaz Jundishpour University of Medical Sciences

Street address
Khuzestan, Ahvaz, Golestan, Ahvaz Jundishpour University of Medical Sciences

City
Ahvaz

Postal code

Approval date
2016-10-22, 1395/08/01

Ethics committee reference number
IR.AJUMS.REC.1395.435

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
K76.0

Primary outcomes

1

Description
ALT

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

2

Description
AST

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

3

Description
FBS

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

4

Description
Total cholesterol

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

5

Description
Triglyceride

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

6

Description
HDL

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

7

Description
LDL

Timepoint
Before and 3 months after intervention

Method of measurement

Blood test

8

Description
CRP
Timepoint
Before and 3 months after intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
Weight
Timepoint
Before and 3 months after intervention
Method of measurement
Scale

2

Description
Body mass index (BMI)
Timepoint
Before and 3 months after intervention
Method of measurement
Body mass is expressed in units of kg/m2

3

Description
Waist
Timepoint
Before and 3 months after intervention
Method of measurement
Centimeter

Intervention groups

1

Description
Two protexin probiotic capsules 600 mg (Probiotics international, United Kingdom) and two zinc sulfate capsules 25 mg (Alhavi, Iran)are used daily, at noon and at night after meals, for three months. The protexin capsule contains 7 species of probiotics. Include Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum and Lactobacillus bulgaricus.
Category
Treatment - Drugs

2

Description
Two protexin probiotic capsules 600 mg (Probiotics international, United Kingdom) and two zinc placebo capsules are used daily, at noon and at night after meals, for three months. The protexin capsule contains 7 species of probiotics. Include Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum and Lactobacillus bulgaricus.
Category
Treatment - Other

3

Description
Two capsules of probiotic placebo and two zinc sulfate capsules 25 mg (Alhavi, Iran) are used daily, at noon and at night after meals, for three months.
Category
Treatment - Other

4

Description
Two probiotic placebo capsules and two zinc placebo capsules are used daily, at noon and at night after meals, for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Dr Masoumeh Khedri
Street address
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Center for Infectious Diseases of the Digestive System, Vice Chancellor research of Ahvaz J
Full name of responsible person
Dr Behzad Sharif Makhmalzadeh
Street address
Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Center for Infectious Diseases of the Digestive System, Vice Chancellor research of Ahvaz J

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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Web page address

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