

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3292 1839

##### Email address

khedri.m@ajums.ac.ir

##### 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/m<sup>2</sup>

## **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**

Dr Masoumeh Khedri

**Position**

Hepatology and gastroenterology fellowship

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**Position**

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**Full name of responsible person**

Dr Masoumeh Khedri

**Position**

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**Other areas of specialty/work****Street address**

Ahvaz Jundishapur University of Medical Sciences

**City****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*