

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effects of probiotic and metformin on nonalcoholic steatohepatitis: a double blind randomized clinical trial.

#### Protocol summary

##### Summary

Effects of probiotic and metformin on nonalcoholic steatohepatitis patients admitted to Al Zahra hospital Sixty three Patients 18-75 years with biopsy-confirmed NASH were enrolled to study. Patients were randomized to one of the following treatments during 6 months: group I, treated with Protexin two tablets per day plus Metformin 500 mg two tablets per day (Met/Pro) and group II, treated with Metformin 500 mg two tablets per day plus two placebo tablet (Met/P). After six month Alanine aminotransferase (ALT), Aspartate aminotransferase, TG, FBS, cholesterol, CBC and ultrasound grading of NASH were measured. Before and after intervention ultrasound was performed to determine of NASH grade by one radiologist (Grade 0 normal, grade 1 mild, grade 2 moderate, grade 3 severe). any participant who will take antibiotics for any indication for more than 1 week during the study period or before recruitment to the study; losing more than 10% of baseline body weight during the study period; autoimmune hepatitis; Wilson's disease; HBV/HCV/HIV/EBV/CMV infection; pregnancy and lactation.

#### General information

##### Acronym

NASH nonalcoholic steatohepatitis

##### IRCT registration information

IRCT registration number: **IRCT201204049376N1**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-07-05, 1391/04/15

#### Registrant information

##### Name

Hassan Firouzian

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1651 1629

##### Email address

hassan\_firouzian@resident.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan University of Medical Sciences

#### Expected recruitment start date

2010-11-21, 1389/08/30

#### Expected recruitment end date

2012-04-19, 1391/01/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effects of probiotic and metformin on nonalcoholic steatohepatitis: a double blind randomized clinical trial.

#### Public title

Effects of probiotic on nonalcoholic steatohepatitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patients admitted to Al Zahra hospital over 18 years, who have NASH confirmed by biopsy.

Exclusion criteria: any participant who will take antibiotics for any indication for more than 1 week during the study period or before recruitment to the study;

losing more than 10% of baseline body weight during the study period; autoimmune hepatitis; Wilson's disease; HBV/HCV/HIV/EBV/CMV infection; pregnancy and lactation

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **63**

#### 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

Isfahan University of Medical Sciences Ethics Committee

##### Street address

Vice Chancellor for Research of medical university of Isfahan.Hezar Jarib Ave, Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2010-10-23, 1389/08/01

#### Ethics committee reference number

391058

## Health conditions studied

### 1

#### Description of health condition studied

Nonalcoholic steatohepatitis

#### ICD-10 code

K75.9

#### ICD-10 code description

Inflammatory liver disease, unspecified Hepatitis NOS

## Primary outcomes

### 1

#### Description

Alanine transaminase (ALT)

#### Timepoint

Before and after treatment

#### Method of measurement

Blood test

### 2

#### Description

Aspartate aminotransferase (AST)

#### Timepoint

before and after treatment

#### Method of measurement

blood test AST

### 3

#### Description

ultrasound Grade of NASH

#### Timepoint

before and after treatment

#### Method of measurement

ultrasound

## Secondary outcomes

### 1

#### Description

fasting blood suger (FBS)

#### Timepoint

before and after treatment

#### Method of measurement

blood test

### 2

#### Description

chlosterol

#### Timepoint

before and after treatment

#### Method of measurement

blood test

### 3

#### Description

triglyceride

#### Timepoint

before and after treatment

#### Method of measurement

blood test

### 4

#### Description

body mass index (BMI)

#### Timepoint

before and after treatment  
**Method of measurement**  
measure weight and height

## Intervention groups

### 1

#### Description

Control group: treated with Metformin 500 mg two tablets per day plus two placebo tablet two tablets per day for six month

#### Category

Behavior

### 2

#### Description

Protexin two tablets per day plus Metformin 500 mg two tablets per day for six month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Alzahra university hospital

**Full name of responsible person**

Hassan Firouzian gastrointestinal fellow

**Street address**

**City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Peiman Adibi

**Street address**

Vice Chancellery for Research, Isfahan University of Medical Sciences, Hezar jarib Ave

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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

#### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Hassan Firouzian

**Position**

Gastrointestinal fellow

**Other areas of specialty/work**

**Street address**

Alzahra university hospital

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**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Ahmad Shavakhi

**Position**

Gastrologist

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

North Khorasan University of Medical Sciences

**Full name of responsible person**

Raheleh Assali

**Position**

Master science/faculty member

**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*