Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

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

Protocol summary

Summary

Effects of probiotic and metformin on nonalcolic steatohepatitisin 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 aminotransferans,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; loosing 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 nonalcolic 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

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Hassan Firouzian
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Isfahan University of Medical Sciences
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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 nonalcolic steatohepatitis: a double blind randomized clinical trial.

Public title

Effects of probiotic on nonalcolic 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;

loosing 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 Isfehan.Hezar Jarib Ave, Isfehan

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 aminotransferse (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
befoer 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

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Alzahra university hospital

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Person responsible for scientific inquiries

Contact

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Gastrologist

Other areas of specialty/work

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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