

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effects of synbiotics supplement on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

Protocol summary

hekmat@sina.tums.ac.ir

Summary

To study the effects of synbiotics supplement on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis (NASH), 50 patients who referred to Gastrointestinal (GI) clinic with steatosis grade 1 or more will be randomly allocated to receive 2 protexin capsules or placebos for 7 months; both groups will be advised to adherence our diet and exercise program too. At the first and the end of the intervention, lipid profiles, liver enzymes, some inflammatory cytokines, and liver fibrosis will be assessed and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012084010N4**

Registration date: **2012-11-30, 1391/09/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0824

Email address

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute (NNFTRI) and Digestive Disease Research Institute (DDRI)

Expected recruitment start date

2012-02-22, 1390/12/03

Expected recruitment end date

2012-09-25, 1391/07/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of synbiotics supplement on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

Public title

The effects of healthy bacteria supplementation on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 years and older; BMI between 25-40; Abnormal serum transferase (ALT & AST more than 1.5 fold of normal range); Sonographic findings compatible with hepatic steatosis (degree 2 or more). Exclusion criteria: Diabetes; Using antibiotic 2 weeks before recruitment to the study; A history of alcohol consumption; Pregnancy & Breast feeding, Professional athletes; Liver disease (viral/etc); Use of

drugs such as calcium channel blockers, high dose synthetic estrogens, methotrexate, amiodarone, steroids, chloroquine, immunosuppressive drugs, lipid-lowering agents, metformin and vitamin E; A history of Hypertension, Cardiovascular disease, Pulmonary disease, Renal disease & Celiac disease; Cirrhosis; Medications causing NAS; Upper GI surgery / Prior surgical procedures such as jejunoileal or jejunocolic bypass, gastropasty, following program to lose weight in recent 3 mo;-A history of hypothyroidism or Cushing's syndrome.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

National Nutrition and Food Technology Research Institute (NNFTRI)

Street address

#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb

City

Tehran

Postal code

1981619573

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

046466

Health conditions studied**1****Description of health condition studied**

Nonalcoholic steatohepatitis (NASH)

ICD-10 code

K75.8

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes**1****Description**

ALT, AST, GGT

Timepoint

at the beginning and at the last

Method of measurement

Biochemistry

2**Description**

hs-CRP, TNF-a

Timepoint

at the beginning and at the last

Method of measurement

ELISA & Nephelometer

3**Description**

liver fibrosis

Timepoint

at the beginning and at the last

Method of measurement

Fibroscan

4**Description**

FBS

Timepoint

at the beginning and at the last

Method of measurement

Biochemistry

5**Description**

cholesterol, TG, LDL-c, HDL-c

Timepoint

at the beginning and at the last

Method of measurement

Biochemistry

Secondary outcomes**1****Description**

weight and BMI

Timepoint

at weeks: 0, 14, 28

Method of measurement

Weight will be measured by Secca scale , BMI by formula

2

Description

waist circumference, hip circumference

Timepoint

at weeks: 0, 14, 28

Method of measurement

non stretch meter

3

Description

insulin

Timepoint

at weeks: 0, 14, 28

Method of measurement

ELISA

4

Description

insulin resistance

Timepoint

at weeks: 0, 28

Method of measurement

formula

Intervention groups

1

Description

intervention: 2 protexin capsules for 7 months

Category

Treatment - Drugs

2

Description

control: 2 placebo capsule (Maltodextrin) for 7 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

GI clinic

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute (NNFTRI)

Full name of responsible person

Dr Hajifaraji

Street address

#7, West Arghavan, Farahzadi BLV, Shahrak Gharb

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research Institute (NNFTRI)

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

National Nutrition and Food Technology Research Institute (NNFTRI)

Full name of responsible person

Dr Azita Hekmatdoost

Position

MD, PhD/ Assistant Prof

Other areas of specialty/work

Street address

#7, West arghavan, Farahzadi Blv, Shahrak Gharb

City

Tehran

Postal code

Phone

+98 21 2235 7484

Fax

Email

a_hekmat2000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

National Nutrition and Food Technology Research Institute (NNFTRI)

Full name of responsible person

Dr Azita Hekmatdoost

Position

MD, PhD/ Assistant Prof

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

#7, West Arghavan, Farahzadi BLv, Shahrak Gharb

City

Tehran

Postal code**Phone**

+98 21 2235 7484

Fax**Email**

a_hekmat2000@yahoo.com

Web page address**Person responsible for updating data****Contact****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