Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

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

Protocol summary

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
hekmat@sina.tums.ac.ir

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, gastroplasty, 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 & Nephlometer

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
cholestrol, 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 circumfereance

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 (Maltodexterin) 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