Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of Effect of Probiotics on Nonalcoholic Fatty Liver Disease in Obese or Overweight Children and Adolescents 10-18 years

Protocol summary

Summary

The purpose of this study was to evaluate the effect of probiotics in non-alcoholic fatty liver disease in children. Children and adolescents with non-alcoholic fatty liver disease, aged 10 to 18 years with a body mass of 85 percent and are selected. Exclusion criteria included alcohol consumption, the presence of other liver diseases and drug history is about. Patients with non-alcoholic fatty liver disease among children with gastrointestinal outpatient clinic of children go to be elected. The sample size is calculated to be at least 64 patients randomly divided into two groups. Pokid capsule orally once daily for the intervention group and the control group received a placebo daily capsule that is similar to the original drug is given for 12 weeks. Before and after intervention liver enzymes and liver ultrasound is done and compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100414882N1**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name

Fatemeh Famouri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

famouri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of Probiotics on Nonalcoholic Fatty Liver Disease in Obese or Overweight Children and Adolescents 10-18 years

Public title

Evaluation of Effect of Probiotics on Nonalcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents with fatty liver disease; 10-18 years; BMI=> 85% Exclusion criteria: alcohol ingestion; other baseline liver disease; ingestion of medication

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **64**
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
Ethic Commitee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Isfahan, Iran
City
Isfahan
Postal code
81746-73461
Approval date
2015-01-21, 1393/11/01
Ethics committee reference number
393891

Health conditions studied

1

Description of health condition studied
non alcoholic fatty liver disease
ICD-10 code
k75.8
ICD-10 code description
nonalcoholic steatohepatitis

Primary outcomes

1

Description
liver aminotransferase level
Timepoint
before and 12 weeks after intervention
Method of measurement
biochemical laboratory testes

2

Description
grade of fatty liver
Timepoint
before and 12 weeks after intervention
Method of measurement
sonography

Secondary outcomes

1

Description
lipid profiles
Timepoint
before and 12 weeks after intervention
Method of measurement
biochemical laboratory testes

Intervention groups

1

Description
The treatment group recieved one prokid capsule daily oral for a duration of 12 weeks.
Category
Treatment - Drugs

2

Description
The placebo group recieved one placebo capsule(similar in shape, color, and size) daily oral for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatrics Gastroenterology Clinic
Full name of responsible person
Dr. Fatemeh Famouri
Street address
Imam Hossein Hospital, Isfahan, Iran
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mansur Siyavash
Street address

Isfahan University of Medical Sciences, Isfahan, Iran

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

Child Growth and Development Center and Pediatic Group of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Zeinab Shariat

Position

Pediatic Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Fatemeh Famouri

Position

Assistant Professor, Gastrointestinal and Hepatology Subspecialist

Other areas of specialty/work

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Full name of responsible person

Dr. Roya Kelishadi

Position

Professor/ Pediatrition

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