

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

+98 31 3663 7291

###### 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 Committee 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 Pediatric Group of Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Zeinab Shariat

**Position**

Pediatric Resident

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Child Growth and Development Centre and Pediatric Group of Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Famouri

**Position**

Assistant Professor, Gastrointestinal and Hepatology

Subspecialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Dr. Roya Kelishadi

**Position**

Professor/ Pediatrics

**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*