Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of sylimarin effect on non alcoholic fatty liver on children and adolescents

Protocol summary

Summary

Objectives: Non alcoholic fatty liver disease is one of the most common liver diseases of adults so that its prevalence is also increasing in children and adolescents. It is the most predisposing factor for liver cirrhosis in adults. Due to complications of non alcoholic fatty liver disease, the treatment of this disease is essential. Recently silymarin is recommended for treatment of non alcoholic fatty liver disease in adults. Since this study have not been done in Iranian children and adolescents, we decided to evaluate the effect of this herbal medication on non alcoholic fatty liver disease in children and adolescents. Design: This is a randomized cross sectional case control double blind clinical trial study, which is done in Shahre-kord University of Medical Science. This study is done on over weight or obese 5-16 years old children and adolescents with evidence of fatty liver in sonography that other causes of fatty liver ruled out for them. Then,Participants were randomized to treatment or placebo groups through random table numbers containing 20 patients in each group. Livergol tablet containing silymarin(Goldaru Company, Iran) were administered for 12 weeks with dosage of 5 mg per kg body weight divided in three dose with meal. However, only changing life style including exercise was advised in the control group. Liver sonography and liver function test are done at arrival to study and after 12 weeks. Participants is followed each months for antropometric measures and compliance to instructions. The first outcome measure changes in sonographic grading of fatty liver. The second outcome measure is liver enzymes changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080614882N4**

Registration date: **2016-09-17, 1395/06/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-17, 1395/06/27

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

Vice chancellor for research, Shahrekord University of Medical Science

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sylimarin effect on non alcoholic fatty liver on children and adolescents

Public title

Effect of sylimarin in treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Obese or overweight child and adolescent with sonographic finding of fatty liver
Exclusion criteria: Age less than 5 and more than 16 years old; patients with metabolic syndromes; viral hepatitis; wilson disease; auto immune hepatitis; juvenile hemochromatosis and other underlying diseases; allergy or intolerance to medication

Age

From **5 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization was done base of random table number

Secondary Ids

1

Registry name

Fatemeh Famouri

Secondary trial Id

14882

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord university of medical science

Street address

University street-Shahrekord

City

Shahrekord

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

14_10_91

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified
Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description

Grading of fatty liver in sonography

Timepoint

At arrival to study and 12 weeks later

Method of measurement

Sonographic grading

Secondary outcomes

1

Description

Liver enzymes, transaminases

Timepoint

At arrival and after 12 weeks

Method of measurement

Serum

Intervention groups

1

Description

intervention group : Livergol tablet containing silymarin(Goldaru Company, Iran) were administered for 12 weeks with dosage of 5 mg per kg body weight divided in three dose with meal. Patients are visited weight, height and compliance to medication each month.

Category

Treatment - Drugs

2

Description

Control group: life style change including increase in physical activity and decease ingestion of fatty and high calori diets.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Out patient department of Hajar hospital, Hajar hospital related to Śhahrekord University of Medica

Full name of responsible person
Dr. Fatemeh Famouri, Pediatric Gastroentrology and Hepatologist

Street address
Shahrekord, Parastar street

City
Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Shahrekord University of Medical Science

Full name of responsible person
Dr. Mahmood Mobasheri

Street address
Shahrekord Setad Daneshgah

City
Shahrekord

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor for Research of Shahrekord University of Medical Science

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 Science

Full name of responsible person
Dr.Fatemeh Famouri

Position
Assistant professor of pediatric gastroenterology and hepat

Other areas of specialty/work

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Person responsible for updating data

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Web page address

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