Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effect of silimarin in children with nonalcoholic fatty liver disease

Protocol summary

Summary

This study aims to investigate the effect of silimarin in overweight, obese and Hyperlipidemic or apparently healthy children who have fatty liver disease manifestations in ultrasound. Liver enzymes, cholesterol and triglycerides are measured and patients are randomly divided into two groups. Patients have a special code and will be studied double-blindly. In case of alcohol drink and receiving hepatotoxic drugs, B, C and autoimmune hepatitis, Wilson's disease, hemochromatosis, alpha-1 antitrypsin, heart and lung diseases and liver cirrhosis, patients are excluded. Patients were divided into two groups and each group of 40 children will be studied. A group receives 140mg silimarin capsule three times a day and the other group receives placebo capsule for three months. After a one month washout period, the groups are displaced to a three-month placebo or silimarin treatment. The groups are age and sex matched. The patients are followed up monthly for drug side effects and drug usage. At the end of 3 months, liver ultrasound and measuring liver enzymes are done and results are collected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012520781N1**
Registration date: **2015-04-04, 1394/01/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-04, 1394/01/15

Registrant information

Name

Hanieh Hajian

Name of organization / entity

Qom University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Qom University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of silimarin in children with nonalcoholic fatty liver disease

Public title

Effect of silimarin on non-alcoholic fatty liver disease in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Obese children with non-alcoholic fatty liver manifestations in ultrasonography. Exclusion criteria : Use of ethanol; use of hepatotoxic drugs; hepatitis B and C; autoimmune hepatitis; Wilson disease; Hemochromatosis; alpha-1 antitrypsin; severe coronary

disease; severe lung disease; liver cirrhosis

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: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qom University of Medical Sciences

Street address
Qom- Saheli Streeet-Qom University of Medical Sciences

City
Qom

Postal code
3719764799

Approval date
2014-12-03, 1393/09/12

Ethics committee reference number
14765/34/پ

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
AST

Timepoint
Before and after the treatment

Method of measurement
mg/dL

2

Description
ALT

Timepoint
Before and after the treatment

Method of measurement
mg/dL

3

Description
Fatty liver disease stage

Timepoint
Before and after the treatment

Method of measurement
Ultrasonography

4

Description
TG

Timepoint
Before and after the treatment

Method of measurement
mg/dL

5

Description
HDL

Timepoint
Before and after the treatment

Method of measurement
mg/dL

6

Description
LDL

Timepoint
Before and after the treatment

Method of measurement
mg/dL

Secondary outcomes

empty

Intervention groups

1

Description
In the case group Silimarin capsule manufactured by

Sabz Daroo company with dose of 140 mg three times a day is used for 3 months

Category

Treatment - Drugs

2

Description

In the control group placebo capsule filled with starch, made by the researcher is used three times a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Masoumeh Hospital

Full name of responsible person

Hanieh Hajian

Street address

Hazrate Masoumeh Hospital, Imam Hassan Mosque, Shahid Zeinoddin Square, Qom, Iran

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi, MD

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd., Qom-Iran

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Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qom 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

Qom University of Medical Sciences

Full name of responsible person

Hanieh Hajian, MD

Position

Resident of Pediatrics

Other areas of specialty/work

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Associate proffessor of Pediatric Gastroenterology

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Other areas of specialty/work

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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