

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3772 7171

##### Email address

hhajian@muq.ac.ir

##### 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 Street-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

**City**

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**

**Street address**

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

**City**

Qom

**Postal code**

**Phone**

+98 25 3612 2952

**Fax**

**Email**

hhajian@muq.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Qom University of Medical Sciences

**Full name of responsible person**

Abolfazl Iranikhah, MD

**Position**

Associate professor of Pediatric Gastroenterology

**Other areas of specialty/work**

**Street address**

Qom University of Medical Sciences - Saheli Street- Qom

**City**

Qom

**Postal code**

**Phone**

+98 25 3612 2952

**Fax**

**Email**

iranikhah@tums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Qom University of Medical Sciences

**Full name of responsible person**

Hanieh Hajian, MD

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

+98 25 3612 2952

**Fax**

**Email**  
**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*