

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the effect of Ursobil and Silymarine in non alcoholic fatty liver

#### Protocol summary

##### Summary

The goal of this study is comparison the effect of Ursobil and Silymarin in treatment of non-alcoholic fatty liver. This study will be performed on 70 patients as double center randomized clinical trial at Velayat and Buali hospitals in Qazvin city. Patients will be selected by randomized method (closed envelopes method and selecting coloured card). Selecting method of patients will be done via sonography confirmation based on fatty liver and increased level of liver enzymes. Persons with Alcoholic cases, hepatotoxic drug users, cases with viral hepatitis and liver metabolic disorder will be excluded. Then patient will be divided into two groups (each include 35 members). Before intervention we will measured liver enzymes, fasting blood sugar, inflammatory marker, lipid profile and serum insulin by laboratory analysis (blood test). After that the first group will be treated with Cap Ursobil 300 mg twice a day and the second group with Tab Silymarin 140mg twice a day for 4 weeks at home. At the end of 4 weeks, we will also measure the pervious parameters and will be compared with baseline values.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040727265N1**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-29, 1395/03/09

##### Registrant information

Name

Nazanin Ghorbanian

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3376 0620

##### Email address

ghorbanian@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2016-03-16, 1394/12/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Ursobil and Silymarine in non alcoholic fatty liver

##### Public title

Comparison of the effect of Ursobil and Silymarine in fatty liver

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Confirmation of NAFLD with ultra sonography; increased level of liver enzymes. Exclusion criteria: Alcoholism; hepatotoxic drug users; viral hepatitis and liver metabolic disorder.

##### Age

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of the Qazvin University of Medical Sciences

**Street address**

Shahid Bahonar Blvd.

**City**

Qazvin

**Postal code**

3419759811

**Approval date**

2016-04-09, 1395/01/21

**Ethics committee reference number**

IR.QUMS.REC.1394.842

**Health conditions studied**

1

**Description of health condition studied**

Nonalcoholic steatohepatitis

**ICD-10 code**

K75.8

**ICD-10 code description**

nonalcoholic steatohepatitis

**Primary outcomes**

1

**Description**

Liver enzymes

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

By laboratory analysis ( blood test)

2

**Description**

Serum insulin

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

Chemiluminescence

3

**Description**

Fasting blood sugar

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

By laboratory analysis ( blood test)

4

**Description**

Lipid profile

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

By laboratory analysis ( blood test)

5

**Description**

Inflammatory marker

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

By laboratory analysis ( blood test)

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

First group will be received Ursobil (oral capsule; 300mg BD for 4 weeks)

**Category**

Treatment - Drugs

2

**Description**

Second group will be received Silymarin (oral tablet ; 140 mg BD for 4 weeks)

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Velayat educational and treatment center

**Full name of responsible person**

Dr. Arash Mirolyae

**Street address**

Velayat Hospital, Taavon Sq., 22 Bahaman Blvd,  
Elahieh

**City**

Qazvin

2

### Recruitment center

**Name of recruitment center**

Buali educational and treatment center

**Full name of responsible person**

Dr. Arash Mirolyae

**Street address**

Buali Hospital, Western Buali Street, Qazvin

**City**

Qazvin

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research Qazvin University of  
Medical Sciences

**Full name of responsible person**

Dr. Taghi Naserpour

**Street address**

Shahid Bahonar Blvd

**City**

Qazvin

**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 Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Nazanin Ghorbanian

**Position**

Medical student

**Other areas of specialty/work**

**Street address**

Medical School, Qazvin University Of Medical  
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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Velayat Educational and Treatment Center

**Full name of responsible person**

Dr. Arash Mirolyae

**Position**

Gastroenterologist

**Other areas of specialty/work**

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## Person responsible for updating data

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nazanin.ghorbanian@yahoo.comvcrc92@yahoo.com

**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*