Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of the effect of Ursobil and Silymarine in non alchoholic 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 alchoholic 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 Mirolyaee

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 Mirolyaee

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

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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

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Position
Medical student

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