# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Effect of Silymarin on Non Alcoholic Steatohepatitis

## Protocol summary

**Summary**

The aim of this clinical trial is to study the effect of Silymarin on non alcoholic steatohepatitis in patients with nonalcoholic fatty liver disease. Fifty patients will be included. They are older than 20 years with nonalcoholic-fatty liver disease and liver enzymes> 50 and proportion of ALT/ AST> 1. The fatty liver will be recognized by sonography. Exclusion criteria are using drugs that affect liver tests during the last 2 months, viral hepatitis, hemochromatosis, autoimmune hepatitis, cirrhosis, diabetes mellitus, alcohol dependency, pregnancy, breast feeding, and infectious diseases. Intervention group will be administrated 140 mg of Silymarin BID during 6 month and control group will be given placebo. Liver enzymes and recovery of liver markers in sonography will be assessed after 6 months of treatment course.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138805172308N1**
Registration date: **2009-09-14, 1388/06/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2009-09-14, 1388/06/23

**Registrant information**

**Name**
Tarang Taghvaei
**Name of organization / entity**
Mazandaran Univercity of Medical Sciences and Health Services
**Country**
Iran (Islamic Republic of)
**Phone**
+98 15 1324 2615
**Email address**
ttaghvaeei@mazums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Mazandaran University of Medical Sciences

**Expected recruitment start date**

2009-08-23, 1388/06/01

**Expected recruitment end date**

2010-04-04, 1389/01/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Silymarin on Non Alcoholic Steatohepatitis

**Public title**

Effect of Silymarin on Non Alcoholic Steatohepatitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Including criteria: older than 20 years with nonalcoholic-fatty liver disease and liver enzymes> 50 and proportion of ALT/ AST> 1 Excluding criteria: using drugs that affect liver tests during the last 2 months, viral hepatitis, hemochromatosis, autoimmune hepatitis, cirrhosis, diabetes mellitus, alcohol dependency, pregnancy, breast feeding, and infectious diseases

**Age**

From **20 years** old to **100 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**
Target sample size: **50**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Mazandaran University of Medical Sciences and Health Services

**Street address**
Imam Sq, Joybar 3way, Start of valiye asr highway

**City**
Sari

**Postal code**

**Approval date**
2009-08-26, 1388/06/04

**Ethics committee reference number**
88-64

## Health conditions studied

### 1

**Description of health condition studied**
Non alcocholic steatohepatitis

**ICD-10 code**
K76.0

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

## Primary outcomes

### 1

**Description**
AST

**Timepoint**
Before and 6 months after the therapy

**Method of measurement**
laboratory

### 2

**Description**
ALT

**Timepoint**
Before and 6 months after the therapy

**Method of measurement**
laboratory

### 3

**Description**
Sonographic markers

**Timepoint**
Before and 6 months after the therapy

**Method of measurement**
by Radiologist

## Secondary outcomes

### 1

**Description**
Weight

**Timepoint**
Before and 6 month after the therapy

**Method of measurement**
balance

### 2

**Description**
BMI

**Timepoint**
Before and 6 months after the therapy

**Method of measurement**
Weight(kg)/height^2(m2)

### 3

**Description**
TG

**Timepoint**
Before and 6 months after the therapy

**Method of measurement**
laboratory

### 4

**Description**
FBS

**Timepoint**
before and 6 months after the therapy

**Method of measurement**
laboratory

## Intervention groups

### 1

**Description**
Intervention group: 140 mg of Silymarin BID during 6 month

**Category**
Treatment - Drugs

**2**

**Description**
Contorol group: placebo
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Tuba clinic
**Full name of responsible person**
Torang Taghvaei
**Street address**
Tuba clinic - Khazar blv.
**City**
Sari

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences and Health Services
**Full name of responsible person**
Sayed Jalal Hosseini mehr
**Street address**
Moalem SQ-2 Building
**City**
Sari
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mazandaran University of Medical Sciences and Health Services
**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**
Mazandaran Univercity of Medical Sciences and Health Services
**Full name of responsible person**
Dr Torang Taghvaei
**Position**
Gastroenterologist/Faculty member
**Other areas of specialty/work**
**Street address**
Imam khomaini hospital-Razi street
**City**
Sari
**Postal code**
**Phone**
+98 15 1226 1700
**Fax**
**Email**
ttaghvaeei@mazums.ac.ir
tarang_taghvaei@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mazandaranl Univercity of Medical Sciences and Health Services
**Full name of responsible person**
Dr Torang Taghvaei
**Position**
Gastroenterologist/faculty member
**Other areas of specialty/work**
**Street address**
Imam Khomani hospital - Razi street
**City**
Sari
**Postal code**
**Phone**
+98 15 1226 1700
**Fax**
**Email**
ttaghvaeei@mazums.ac.ir
tarang_taghvaei@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences and Health Services
**Full name of responsible person**
Millad Kasraei
**Position**
Medecine student
**Other areas of specialty/work**
**Street address**
Imam khomaini hospital - Razi street
**City**
Sari
**Postal code**
**Phone**
**Fax**
**Email**
milladxkz@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*