

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 15 1324 2615

Email address

ttaghvaei@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)/height²(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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Torang Taghvaei

Position

Gastroenterologist/faculty member

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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

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milladxkz@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty