Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)
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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
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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
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
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Full name of responsible person
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Person responsible for updating data

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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