Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Evaluation of effect of silymarin and vitamin E on liver enzyme of nonalcoholic steatohepatitis patients: results of a randomized clinical trial

Protocol summary

Summary

The aim of this study was to evaluate the effect of silymarin and vitamin E on liver enzymes of non-alcoholic steatohepatitis patients who referred to Shahid Mofatte Clinic of Yasuj in 2016-2017. Patients who had evidence of non-alcoholic steatohepatitis in sonography and increased liver enzymes were included in the study. Secondary causes of elevated liver enzymes were also excluded. This clinical trial study was performed on 114 patients with non-alcoholic steatohepatitis. Patients were randomly allocated into three groups (1.1.1 ratio) and treated with silymarin; vitamin E; vitamin E and silymarin for 3 months. Diet and exercise program were recommended to all patients. Before and after treatment for all patients, liver enzymes were measured and compared in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111322869N2**
Registration date: **2017-08-30, 1396/06/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-30, 1396/06/08

Registrant information

Name

Moslem Sedaghattalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0163

Email address

m.sedaghattalab@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yasuj University of Medical Science

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of silymarin and vitamin E on liver enzyme of nonalcoholic steatohepatitis patients: results of a randomized clinical trial

Public title

Evaluation of effect of Livergol and vitamin E on liver enzyme of nonalcoholic steatohepatitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Major inclusion criteria: Diagnosis of non-alcoholic steatohepatitis disease by sonography and elevated liver enzymes; negative history of autoimmune hepatitis, viral hepatitis, Wilson disease, hemochromatosis, α-1 antitrypsin deficiency, diabetes, hypothyroidism, cardio-pulmonary disease, kidney disease, psychiatric disease, pregnancy, alcohol consumption; also negative history

for using lipid lowering drugs such as atorvastatin and gemfibrozil, estrogen, tamoxifen, corticosteroids, amiodarone, acetaminophen more than 2 grams per day, chemotherapy drugs in six months ago, anti-seizure medications such as sodium valproate, carbamazepine, phenytoin, anti-tuberculosis drugs such as isoniazid, rifampin, perazinamide. Major exclusion criteria: Patient’s displeasure to continue participation in the study; The incidence of drug-related complications.

Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **114**
Randomization (investigator's opinion)
N/A
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 Yasuj University of Medical Science
Street address
Yasuj University of Medical Science, Motahari street, Yasuj city
City
Yasuj
Postal code
75917-41417
Approval date
2016-12-27, 1395/10/07
Ethics committee reference number
IR.YUMS.1395.134

Health conditions studied

1

Description of health condition studied
fatty liver disease
ICD-10 code
K75.8
ICD-10 code description
nonalcoholic steatohepatitis

Primary outcomes

1

Description
aspartate aminotransferase
Timepoint
3 month
Method of measurement
International Unit per Milliliter

2

Description
alanine aminotransferase
Timepoint
3 month
Method of measurement
International Unit per Milliliter

Secondary outcomes

1

Description
Drug reaction
Timepoint
3 month
Method of measurement
Questionnaire

Intervention groups

1

Description
silymarin, tablet 140 milligram parenteral, daily for 3 month
Category
N/A

2

Description
Vitamin E,tablet 400 unit parenteral, daily for 3 month
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofatte clinic
Full name of responsible person

moslem sedaghattalab

Street address

Yasuj, Shahrdari street, Shahid Mofatte clinic

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Yasuj University of Medical Sciences

Full name of responsible person

Moslem Sedaghattalab

Street address

Yasuj University of Medical Sciences, Motahari street, Yasuj city

City

Yasuj

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 of Yasuj 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

Yasuj University of Medical Science

Full name of responsible person

Moslem Sedaghattalb

Position

Assiatant professor

Other areas of specialty/work

Street address

Emam Sajad hospital, Dr.Jalil street, Yasuj city

City

Yasuj

Postal code

Phone

+98 74 3322 0163

Fax

Email

m.sedaghattalab@yums.ac.ir; moslem.sedaghattalab@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Science

Full name of responsible person

Moslem Sedaghattalab

Position

Assiatant professor

Other areas of specialty/work

Street address

Emam Sajad hospital, Dr.Jalil street, Yasuj city

City

Yasuj

Postal code

Phone

+98 74 3322 0163

Fax

Email

m.sedaghattalab@yums.ac.ir; moslem.sedaghattalab@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yasuj University of Medical Science

Full name of responsible person

Moslem Sedaghattalb

Position

Assiatant professor

Other areas of specialty/work

Street address

Emam Sajad hospital, Dr.Jalil street, Yasuj city

City

Yasuj

Postal code

Phone

+98 74 3322 0163

Fax

Email

m.sedaghattalab@yums.ac.ir; moslem.sedaghattalab@gmail.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