Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The Efficacy of Silymarin and Vitamin E in the Treatment of the Non-Alcoholic Fatty Liver Disease: A Clinical Trial

Protocol summary

Study aim

The present study is an attempt to evaluate the efficacy and safety of oral silymarin as compared to Vitamin E administered to subjects with NAFLD in a treatment period of four months.

Design

The inclusion criteria were NAFLD confirmed through abdominal ultrasonography, persistent elevation in the level of alanine aminotransferase (ALT) within the last six months for one and a half times more than the upper normal limit, fatty changes diagnosed through ultrasonography, and over 20 years of age.

Settings and conduct

This clinical trial was performed on eighty NAFLD patients who had referred to the Gastroenterology clinic of the Medical University in Yazd, Iran, from September 2014 to March 2015.

Participants/Inclusion and exclusion criteria

The inclusion criteria were NAFLD confirmed through abdominal ultrasonography, persistent elevation in the level of alanine aminotransferase (ALT) within the last six months for one and a half times more than the upper normal limit, fatty changes diagnosed through ultrasonography, and over 20 years of age. The exclusion criteria were autoimmune hepatitis, alpha-1 antitrypsin deficiency, chronic hepatitis B or C, hemochromatosis, and Wilson's disease. Patients with a history of diabetes, daily consumption ethanol, severe cardiac, pulmonary, renal, or psychological problems, positive pregnancy test, and the use of drugs such as statins,

Intervention groups

In this study , eighty NAFLD patients were assigned to two groups of forty. Those in the first group received vitamin E 400 UI /day, and those in the second group were given silymarin 140 mg bid (livergol-Goldaro Company)

Main outcome variables

They were received at the baseline and then after four months for ALT measurements and ultrasonographic evaluations of their liver.

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20081110001444N6**
Registration date: **2019-11-02, 1398/08/11**
Registration timing: **retrospective**

Last update: **2019-11-02, 1398/08/11**
Update count: **0**

Registration date

2019-11-02, 1398/08/11

Registrant information

Name

mohsen akhondi meybodi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 5825

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

2014-05-01, 1393/02/11

Actual recruitment end date
2015-08-30, 1394/06/08
Trial completion date
2016-08-01, 1395/05/11

Scientific title
The Efficacy of Silymarin and Vitamin E in the Treatment of the Non-Alcoholic Fatty Liver Disease: A Clinical Trial

Public title
Efficacy of Silymarin and Vitamin E in the Treatment fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The inclusion criteria were : NAFLD confirmed through abdominal ultrasonography, persistent elevation in the level of alanine aminotransferase (ALT) within the last six months for one and a half times more than the upper normal limit, fatty changes diagnosed through ultrasonography, and over 20 years of age.
Exclusion criteria:
The exclusion criteria were autoimmune hepatitis, alpha-1 antitrypsin deficiency, chronic hepatitis B or C, hemochromatosis, and Wilson's disease. Patients with a history of diabetes, daily consumption ethanol, severe cardiac, pulmonary, renal, or psychological problems, positive pregnancy test, and the use of drugs such as statins, fibrates, anti-convulsants, NSAID, acetaminophen, warfarin, metronidazole, anti-depressants, or anti-psychotics were also excluded from the study.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were received so as to take daily doses of vitamins E (400 IU) and Silymarin 140 mg BID (with the brand name of Livergol from Goldaru Pharmaceutical Company, Iran) for four months. Additionally, they were all given consultation for standard weight-loss programs and persuaded to follow low-fat diets
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients were received so as to take daily doses of vitamins E (400 IU) and Silymarin 140 mg BID (with the brand name of Livergol from Goldaru Pharmaceutical Company, Iran) for four months. Additionally, they were all given consultation for standard weight-loss programs and persuaded to follow low-fat diets
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sadoughi University of Medical Sciences-Yazd, Iran
Street address
bahonar squre
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2014-07-23, 1393/05/01
Ethics committee reference number
IR.SSU.MEDICINE.REC.1393.114

Health conditions studied

1

Description of health condition studied
Non-Alcoholic Fatty Liver Disease
ICD-10 code
K75.81
ICD-10 code description
Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
ALanin aminotransferas measurements
Timepoint
They were received at the baseline and then after four months for ALT measurements
Method of measurement
autoanlizer

2

Description
ultrasonographic evaluations of their liver
Timepoint
first and four months later

Method of measurement
General Electric ultrasound device,

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 silymarin: Silymarin 140 mg BID (with the brand name of Livergol from Goldaru Pharmaceutical Company, Iran) for four months.Additionally, they were all given consultation for standard weight-loss programs and persuaded to follow low-fat diets (< 30 fat g/day). They were received at the baseline and then after four months for ALT measurements and ultrasonographic evaluations of their liver
Category
Treatment - Drugs

2

Description
Intervention group 2: vitamin E The patients were receivedso as to take daily doses of vitamins E (400 IU) for four months. Additionally, they were all given consultation for standard weight-loss programs and persuaded to follow low-fat diets (< 30 fat g/day). They were received at the baseline and then after four months for ALT measurements and ultrasonographic evaluations of their liver. In these evaluations, which were performed with a General Electric LOGIQ 400 CL ultrasound device.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology clinic of the Medical University in Yazd,
Full name of responsible person
Mohsen akhondi-Meybodi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Sadoughi University of Medical Sciences-Yazd, Iran
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
mohsen akhondi-Meybodi
Position
Associate professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
all of data can be publish or sharing with coalleagues
When the data will become available and for how long
irct 5 years
To whom data/document is available
professors that study NASH
Under which criteria data/document could be used
use in review article
From where data/document is obtainable
mohsen akhondi
What processes are involved for a request to access data/document
by email request
Comments