

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Nutri Liver Support on liver enzyme level and lipid profile of non alcoholic fatty liver patients.

Protocol summary

2015-06-04, 1394/03/14

Summary

The aim of this project is to investigate effect of Silymarin which is the main active substance of Nutri Liver Support for treating NAFLD. Method : In this randomized double-blind clinical trial study, 80 patients with NAFLD who referred to Gastrointestinology Clinic of Kowsar Hospital of Semnan -after getting their informed consent- will be enrolled based on inclusive criteria: patients who are 20 to 40 years old; white skin; whom fatty liver is reported in their sonography; and ALT level above 40. The patients who are subjected to exclusive criteria: Cirrhosis is reported in sonography; Patients who are detected as: Wilson, Autoimmune Hepatitis, viral Hepatitis, Alcoholic Hepatitis, and Hemochromatosis; Patients who are suffering from chronic liver disease; Drug causes is to be considered for fatty liver; drug sensitivity; those who are affected by drug side effects will be excluded from the study. The patients will be randomly divided into two groups of forty cases : 1) Test group will be treated by Nutri Liver Support 150 mg twice a day for two months, and, 2)Control group will be treated by Placebo. Both of them will receive routine treatment including modifying dyslipidemia and modifying Lifestyle. Biochemical experiment on lipid profile and liver enzymes (AST and ALT) will be performed on all patients before and after intervention.

Registrant information

Name

Somayeh Chahkandi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

s_chahkandi@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031721502N1**

Registration date: **2015-06-04, 1394/03/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

Effect of Nutri Liver Support on liver enzyme level and lipid profile of non alcoholic fatty liver patients.

Public title

Effect of Nutri Liver Support in non alcoholic fatty liver patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 to 40 years old; patients who has white skin; patients who referred to the

clinic for checkup; fatty liver is reported in sonography; agreement to be a part of the study; ALT level above 40. Exclusion criteria: patients that want to withdraw the study at any time; cirrhosis is reported in sonography; patients who are detected as Wilson, autoimmune hepatitis, viral hepatitis, alcoholic hepatitis, hemochromatosis; patients who are suffering from chronic liver disease; drug causes is to be considered for fatty liver; sensitive to drug; those who are affecting by drug side effects.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan, Iran

City

Semnan

Postal code

3519899951

Approval date

2015-03-17, 1393/12/26

Ethics committee reference number

104

Health conditions studied**1****Description of health condition studied**

Non Alcoholic Fatty liver Disease

ICD-10 code

k 75.8

ICD-10 code description

Other specified inflammatory liver diseases Nonalcoholic steatohepatitis (NASH)

Primary outcomes**1****Description**

Alanine Aminotransferase

Timepoint

before and after intervention

Method of measurement

serum

2**Description**

Aspartate Aminotransferase

Timepoint

before and after intervention

Method of measurement

serum

Secondary outcomes**1****Description**

level of serum cholesterol

Timepoint

before and after intervention

Method of measurement

serum

2**Description**

Level of serum Triglyceride

Timepoint

Before & after intervention

Method of measurement

Serum

3**Description**

Low-density Lipoprotein

Timepoint

Before & after intervention

Method of measurement

Serum

4**Description**

High-density Lipoprotein

Timepoint

Before & after intervention

Method of measurement

Serum

Intervention groups

1

Description

Nutri Liver Support 150 mg, oral, twice a day for 2 months

Category

Treatment - Drugs

2

Description

placebo, oral, twice a day for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University Gastrointestlinology Clinic

Full name of responsible person

Dr Reza Dabiri

Street address

Semnan University Medical Center, Sadi Sq, Montazeri St, Semnan, Iran

City

Semnan

2

Recruitment center

Name of recruitment center

Kosar Hospital Gastrointestlinology Clinic

Full name of responsible person

Dr Reza Dabiri- Assistant professor of Gastrointestlinology

Street address

Kosar Hospital, Basij Blvd, Semnan,Iran

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University Of Medical Sciences

Full name of responsible person

Dr Ali Rashidi pour

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan, Iran

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Reza Dabiri

Position

Assistant professor of Gastrointestlinology - Faculty member

Other areas of specialty/work

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan, Iran

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7844

Fax

+98 23 3343 7838

Email

Dabirirzf@yahoo.com somayehch49@yahoo.com

Web page address

www.sem-ums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Reza Dabiri

Position

Assistant professor of Gastrointestlinology - Faculty member

Other areas of specialty/work

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan, Iran

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7844

Fax

+98 23 3343 7838

Email

dabirirzf@yahoo.com somayehch49@yahoo.com

Web page address

www.sem-ums.ac.ir

Postal code

3519899951

Phone

+98 23 3343 7844

Fax

+98 23 3343 7838

Email

Dabirirzf@yahoo.com

Web page address

www.sem-ums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Dr Reza Dabiri

Position

Assistant professor of Gastrointestinology - Faculty member

Other areas of specialty/work**Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan, Iran

City

Semnan

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*