Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

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

Protocol summary

Summary

The aim of this project is to investigate effect of Silymarin which is the main active substance of Neutri 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; whitey 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 Neutri 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.

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

2015-06-04, 1394/03/14

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

Scientific title

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

Public title

Effect of Nutri Liver Support in non alchoholic 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 dey 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 Gastrointestinology 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 Gastrointestinology Clinic
Full name of responsible person
Dr Reza Dabiri- Assistant professor of Gastrointestinology
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 Gastrointestinology - 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 Gastrointestinology - 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 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
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

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