Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Nov 2026

The effect of folate supplementation on serum hepatic enzymes, lipid profile and homocystein levels in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Protocol summary

Summary

The aim of the study is evaluation of the effect of folate supplementation on serum hepatic enzymes, lipid profile and homocystein levels in patients with Non-Alcoholic Fatty Liver Disease. Study design is double blind placebo controlled randomized clinical trial. The study sample includes 40 male patients (20 in intervention and 20 in control group) diagnosed with non alcoholic fatty liver disease. Inclusion Criteria : diagnosis to have non alcoholic fatty liver disease, ages above 18 and serum alanine transaminase enzyme level higher than 30 U/L . Exclusion criteria: Alcohol consumption greater than 20 g per day, having other hepatic diseases, using hepatotoxic drugs and consumption of folate, B12, vitamin E and omega-3 supplementation during last 6 months. Intervention: One tablet of folate supplement contains 1 mg folic acid will be prescribed daily for 8 weeks in intervention group. One tablet placebo contains starch will be prescribed daily for 8 weeks in control group. Primary Outcomes: Serum levels of alanine transaminase and grade of fatty liver based on ultrasonography. Secondary Outcomes: serum levels of lipid profile and homocystein.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051710333N2**
Registration date: **2015-10-27, 1394/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

Nasrin Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5562 0608

Email address

sharifi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University Of Medical Sciences

Expected recruitment start date

2015-10-17, 1394/07/25

Expected recruitment end date

2015-12-16, 1394/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of folate supplementation on serum hepatic enzymes, lipid profile and homocystein levels in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Public title

The effect of folate supplementation on Non Alcoholic Fatty Liver Disease treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis to have non alcoholic fatty

liver disease confirmed with ultrasonography result; ages above 18 ; serum alanine transaminase enzyme level higher than 30 U/L ; Diabetic patients will include if they have been recently diagnosed with diabetes and not using blood glucose lowering drugs or if they consume insulin and metformin, it would pass at least 6 months from starting the treatment and during this period the dose of metformin and insulin are not changed. Exclusion criteria: Alcohol consumption greater than 20 g per day; diseases such as hereditary hemochromatosis; Wilson's disease; an enzyme deficiency α1 Antitripsin; history of jejunoileal bypass surgery or gastroplasty; experience to perform the total parenteral nutrition at 6 months before; consomption of statins and hepatotoxic drugs such as calcium channel blocker; methotrexate; amiodarone; chloroquine; a history of hypothyroidism and Cushing's syndrome; Intake of folate; B12; vitamin E; omega-3 supplements during last 6 months.

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences

Street address
Ilam University of Medical Sciences, Pajoohesh Blvd.

City
Ilam

Postal code

Approval date
2015-09-29, 1394/07/07

Ethics committee reference number
IR.MEDILAM.REC.1394.285

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver

Primary outcomes

1

Description
Serum Alanine Transaminase

Timepoint
Before and after intervention

Method of measurement
U/L - Laboratory kit

2

Description
Grade of fatty liver based on ultrasonography results

Timepoint
Before and after intervention

Method of measurement
Ultrasonography scan

Secondary outcomes

1

Description
Serum Total cholestrol

Timepoint
Before and after intervention

Method of measurement
mg/dL - Laboratory kit

2

Description
Serum LDL-C

Timepoint
Before and after intervention

Method of measurement
mg/dL- laboratory kit

3

Description
Serum HDL-C

Timepoint
Before and after intervention

Method of measurement
mg/dL- laboratory kit

4

Description
Serum Homocystein
Timepoint
Before and after intervention
Method of measurement
Laboratory kit-umol/Liter

5

Description
Serum Triglyceride
Timepoint
Before and after intervention
Method of measurement
mg/dL- Laboratory kit

6

Description
Serum Aspartate Transaminase (AST)
Timepoint
Before and after intervention
Method of measurement
U/L- laboratory kit

Intervention groups

1

Description
Intervention: Tablet contains 1 mg folate, once a day for 8 weeks
Category
Treatment - Drugs

2

Description
Control: One placebo tablet contains edible starch, once a day for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical Clinic of Ilam Petrochemical Company
Full name of responsible person
Dr. Gharib Reza Younessi
Street address
Ilam Petrochemical Company, Chavar, Ilam
City
Ilam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr. Behzad Badakhsh
Street address
Vice Chancellor for Research and Technology, Ilam University of Medical Sciences
City
Ilam
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Vice Chancellor for Food and Drug, Ilam University of Medical Sciences
Full name of responsible person
Soheila Samieepour
Position
MSc / Expert of food staff and beverages
Other areas of specialty/work
Street address
Vice Chancellor for Food and Drug, IlamUniversity of Medical Sciences, Shahid Keshvari Sq.
City
Ilam
Postal code
Phone
+98 84 3223 2523
Fax
Email
sarma1364@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person

Nasrin Sharifi

Position

Ph.D / Assistant Professor of Nutrition Sciences

Other areas of specialty/work

Street address

Faculty of Medicine, Kashan University of Medical Sciences, Ghotb Ravandi Blvd

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

sharifi.nsr@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Vice Chancellor for Food and Drug, Ilam University of Medical Sciences

Full name of responsible person

Soheila Samieepour

Position

MSc / Expert of food staff and beverages

Other areas of specialty/work

Street address

Vice Chancellor for Food and Drug, Ilam University of Medical Sciences, Shahid Keshvari Sq.

City

Ilam

Postal code

Phone

+98 84 3223 2523

Fax

Email

sarma1364@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