

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

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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 α 1 Antitripsin; history of jejunoileal bypass surgery or gastroplasty; experience to perform the total parenteral nutrition at 6 months before; consumption 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

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Person responsible for scientific inquiries

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Position

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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