Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of folic acid in the treatment of non-alcoholic fatty liver in patients with hepatic fibrosis

Protocol summary

Study aim
Evaluation of the effect of folic acid on liver fibrosis and liver function in patients with nonalcoholic fatty liver grade 2 and 3

Design
A randomized controlled clinical trial with parallel design. Total sample size will be 60 and randomization will be done based on the sequences of the random blocks using statistical software.

Settings and conduct
Patients with fatty liver disease will be evaluated for the study inclusion criteria at the gastroenterology clinic of Qom University of Medical Sciences. Liver sonography, fibroscan and biochemical tests measured at baseline and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are diagnosed to have non alcoholic fatty liver disease confirmed with ultrasonography and fibroscan results; Ages between 18-65 years; Serum alanine transaminase enzyme level higher than 30 U/L Exclusion criteria: Pregnancy; Lactation; Alcohol consumption; Having diseases such as hereditary hemochromatosis and Wilson's disease; History of receiving total parenteral nutrition during last 6 months; Consumption of statins and hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine; Intake of folate, B12, vitamin E and omega-3 supplements during the last 6 months

Intervention groups
The intervention group will receive one tablet contains 5 mg folic acid daily for 24 weeks. The control group will receive one tablet of placebo daily for 24 weeks.

Main outcome variables
A change in the grade of liver fibrosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150819023685N2**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **prospective**

Last update: **2020-02-22, 1398/12/03**
Update count: **0**

Registration date
2020-02-22, 1398/12/03

Registrant information

Name
Samira Khani

Name of organization / entity
Qom University of Medical Science

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Iran (Islamic Republic of)

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+98 25 3783 2370

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of folic acid in the treatment of non-alcoholic fatty liver in patients with hepatic fibrosis

Public title
Efficacy of folic acid in the treatment of non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are diagnosed to have non alcoholic fatty liver disease (grade 2 and 3) confirmed with ultrasonography and fibroscan results. Ages between 18-65 years Serum alanine transaminase enzyme level higher than 30 U/L
Exclusion criteria:
Having diseases such as liver disease and decompensated Cirrhosis Having diseases such as hereditary hemochromatosis and Wilson's disease Consumption of statins and hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone and chloroquine Intake of folate, B12, vitamin E and omega-3 supplements during the last 6 months History of receiving total parenteral nutrition during last 6 months Pregnancy Lactation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to the intervention or control group in the random blocks based on the random number table. The sequence of permuted blocks will be generated with a random number table. An individual with no clinical involvement in the trial, puts the lable of intervention or control group in an opaque and sealed envelope based on the random sequence. Then the other person, who is not aware of random sequences and the envelope content, will assign the patients to the intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present study, participants, clinical caregiver, principal investigator, data analyzer and outcome evaluator will be blinded to the allocation to study groups.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
No. 83, 4th alley, 1.1 alley, Safashahr Blvd
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Province
Ghoum
Postal code
3716987366
Approval date
2019-11-12, 1398/08/21
Ethics committee reference number
IR.MUQ.REC.1398.148

Health conditions studied

1

Description of health condition studied
Nonalcoholic steatohepatitis
ICD-10 code
K75.81
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver stiffness
Timepoint
At baseline and 24 weeks after the start of the intervention
Method of measurement
Fibroscan

Secondary outcomes

1

Description
Blood levels of liver enzymes
Timepoint
At baseline and 24 weeks after the start of the intervention
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Folic acid tablet, 5 mg, oral, once a day, for 6 months
Category
Treatment - Drugs

2

Description
Control group: placebo tablet, oral, once a day, for 6months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hosbital
Full name of responsible person
Ahmad Hormati
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Sponsors / Funding sources

1

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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
Ghoum University of Medical Sciences
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
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assistant 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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is 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
A portion of the data regarding demographics variables, that are collected at the baseline of the study, and also the information on the main outcome will be shared.

When the data will become available and for how long
The start of the data access period will be one year after the publication of the results.

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
In order to conduct meta analysis studies

From where data/document is obtainable
Samira Khani, Pharmacology Department, School of Medicine, Qom University of Medical Sciences, Ghadir Blvd., Qom, Iran Postal Code: 3736175513 E-mail: pharma_75@yahoo.com Tel: 00982533209071

What processes are involved for a request to access data/document
An applicant can send a request for a data file by e-mail. After reviewing the request, the data file will be sent to him/her after about three weeks would have passed from the date of the request.

Comments