Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of vitamin B12 supplement with placebo on grade of liver steatosis and fibrosis based on the results of elastography in patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Study aim

Comparison of the effect of vitamin B12 supplement with placebo on grade of liver steatosis and fibrosis based on the results of elastography in patients with Non-Alcoholic Fatty Liver Disease

Design

A randomized controlled clinical trial with parallel design. Total sample size will be 40 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 Kashan University of Medical Sciences. Liver elastography, anthropometric indices 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 result; Ages between 18-80 years; Serum alanine transaminase enzyme level higher than 30 U/L in men and higher than 19 U/L in women. Exclusion criteria: Pregnancy; Lactation; Alcohol consumption; Having diseases such as hereditary hemochromatosis, Wilson's disease and α1 antitripsin enzyme deficiency; History of jejunoileal bypass surgery and 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 3 months

Intervention groups

The intervention group will receive one tablet contains 1000 microgram vitamin B12 daily for 12 weeks. The control group will receive one tablet of placebo daily for 12 weeks.

Main outcome variables

A change in grade of liver steatosis and fibrosis; changes in serum levels of alanine transaminase and aspartate transaminase; change in insulin resistance; changes in serum levels of malondialdehyde and C-reactive protein

General information

Reason for update

The change in the device of assessing hepatic steatosis and fibrosis

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010333N5**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **prospective**

Last update: **2021-05-06, 1400/02/16**
Update count: **1**

Registration date

2019-12-25, 1398/10/04

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

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vitamin B12 supplement with placebo on grade of liver steatosis and fibrosis based on the results of elastography in patients with Non-Alcoholic Fatty Liver Disease

Public title

Effect of vitamin B12 in treatment of fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are diagnosed to have non alcoholic fatty liver disease confirmed with ultrasonography result Ages between 18-80 years Serum alanine transaminase enzyme level higher than 30 U/L in men Serum alanine transaminase enzyme level higher than 19 U/L in women

Exclusion criteria:

Pregnancy Lactation Alcohol consumption greater than 20 g per day Having diseases such as hereditary hemochromatosis, Wilson's disease and α1 antitripsin enzyme deficiency History of jejunoileal bypass surgery or gastroplasty History of receiving total parenteral nutrition during last 6 months Consumption of statins and hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine History of hypothyroidism and Cushing's syndrome Intake of folate, B12, vitamin E and omega-3 supplements during the last 3 months

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **40**

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 Kashan University of Medical Sciences

Street address

Pezeshk Ave., Qotb-e-Ravandi Blvd.

City

Kashan

Province

Isfehan

Postal code

88715973474

Approval date

2019-11-18, 1398/08/27

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.088

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Grade of liver steatosis

Timepoint

At baseline and 12 weeks after the start of the intervention

Method of measurement

The real-time 2-dimensional shear wave elastography device

2

Description
Grade of liver fibrosis
Timepoint
At baseline and 12 weeks after the start of the intervention
Method of measurement
The real-time 2-dimensional shear wave elastography device

3

Description
Serum level of alanine transaminase
Timepoint
At baseline and 12 weeks after the start of the intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

4

Description
Serum level of aspartate transaminase
Timepoint
At baseline and 12 weeks after the start of the intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

5

Description
Serum level of homocystein
Timepoint
At baseline and 12 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

6

Description
Insulin resistance
Timepoint
At baseline and 12 weeks after the start of the intervention
Method of measurement
By the formula of homeostatic model assessment

Secondary outcomes

1

Description
Serum level of C-reactive protein
Timepoint
At baseline and 12 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

2

Description
Serum level of malondialdehyde
Timepoint
At baseline and 8 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

3

Description
Serum level of low density lipoprotein cholesterol
Timepoint
At baseline and 12 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

4

Description
Serum level of high density lipoprotein cholesterol
Timepoint
At baseline and 12 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

5

Description
Serum level of triglyceride
Timepoint
At baseline and 12 weeks after the start of intervention
Method of measurement
Laboratory clinical kit and analyzer instrument

Intervention groups

1

Description
Intervention group: The intervention group will receive one tablet contains 1000 microgram vitamin B12 daily for 12 weeks.
Category
Treatment - Other

2

Description
Control group: The control group will receive one tablet of placebo contains 1 mg maltodexterin daily for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology clinic of Shahid Beheshti Hospital

Full name of responsible person
Mohammad Reza Mollaghanbari
Street address
Pezeshk Ave., Qotb-e-Ravandi Blvd.
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Email
mollaghanbari-mr@kaums.ac.ir

2

Recruitment center
Name of recruitment center
Radiology center of Shahid Beheshti Hospital
Full name of responsible person
Hamidreza Talari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
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8715988141
Phone
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Email
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Talari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiology
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Person responsible for scientific inquiries

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Full name of responsible person
Nasrin Sharifi
Position
Assistant professor
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Other areas of specialty/work
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Email

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Nasrin Sharifi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Postal code

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Email

sharifi-na@kaums.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the data regarding demographics, anthropometric, and food 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

Nasrin Sharifi, Nutrition Department, School of Medicine, Kashan University of Medical Sciences, Qotbe-e-Ravandi Blvd., Kashan, Iran Postal Code: 88715973474 E-mail: sharifi-na@kaums.ac.ir Tel: 00983155540021 Fax: 00983155620608

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