Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The Effect of Vitamins B6, B9, B12 Supplementation on Liver Enzymes, Inflammatory and Oxidative Stress Markers, Insulin Resistance, Lipid Profile and Serum Homocysteine in Overweight or Obese Patients with Nonalcoholic Fatty Liver Disease

Protocol summary

Study aim
Evaluating the effect of vitamins B6, B9, B12 supplementation on liver enzymes, inflammatory and oxidative stress markers, insulin resistance, lipid profile and serum homocysteine in overweight or obese patients with nonalcoholic fatty liver disease

Design
In a randomized, double-blind, placebo-controlled clinical trial with two parallel groups, fifty eligible patients with NAFLD will be supplemented with either a combination tablet of vitamin B6 (20mg), vitamin B9 (1mg), vitamin B12 (50mcg) or placebo tablet daily for 8 weeks. In both groups, patients will be advised to follow a low-calorie diet and physical activity recommendations. The anthropometric and biochemical parameters will be measured at the baseline and the end of the 8th week.

Settings and conduct
This study will be conducted at Shahid Motahari clinic affiliated to Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria
Overweight or obese patients with nonalcoholic fatty liver disease who dont meet exclusion criteria

Intervention groups
combination tablet of vitamin B6 (20mg), vitamin B9 (1mg), vitamin B12 (50mcg) or placebo tablet

Main outcome variables
Biochemical parameters including liver enzymes, inflammatory markers, oxidative stress markers, insulin resistance, lipid profile, homocysteine and anthropometric parameters including body mass index (BMI), waist–hip ratio (WHR)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180908040972N1**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**

Registration date
2019-01-19, 1397/10/29

Registrant information

Name
Nazanin Mohammadipoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3751 0016

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-01, 1397/07/09

Expected recruitment end date
2019-05-19, 1398/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vitamins B6, B9, B12 Supplementation on

Liver Enzymes, Inflammatory and Oxidative Stress Markers, Insulin Resistance, Lipid Profile and Serum Homocysteine in Overweight or Obese Patients with Nonalcoholic Fatty Liver Disease

Public title
The Effect of Vitamins B6, B9, B12 Supplementation in Treatment of Nonalcoholic Fatty Liver Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in study Age range from 25 to 65 years Body mass index (BMI) from 25 to 40 kg /m2 Serum alanine aminotransferase (ALT) greater than the upper reference limit and steatosis grade > 1 on ultrasonography

Exclusion criteria:
Alcohol abuse (more than 20 grams per day in women and 30 grams per day in men) Acute and chronic liver diseases (all types of hepatitis، biliary disease، cirrhosis، inherited disorders affecting liver condition such as storage disease of iron, and copper، etc.) Gastrointestinal diseases (gastritis, celiac, steatorrhea, crohn, colitis, gastrointestinal bypass surgery, etc.) Hypertension and cardiovascular diseases Renal disease, lung disease, autoimmune diseases, rheumatoid arthritis, multiple sclerosis, cancer, thyroid disorders, epilepsy, diabetes All types of anemia, thalassaemia, A-beta-lipoproteinemia, hypoalbuminemia Hereditary disorders in homocysteine metabolizing enzymes Hepatotoxic drugs, gastric acid suppression drugs, antiepileptic drug and medications such as corticosteroids, contraceptive pills estrogen, progesterone, androgen, levodopa, cycloserine, phenelzine, isoniazid, penicillamine, sulfasalazine Weight loss during the last 6 months Follow special diet (weight loss diet, vegeterian diet, etc.) History of weight loss surgery in the last year Taking any dietary or herbal supplements during the last 6 months History of allergy or intolerance or unlikely side effects from taking vitamins B6، B9، B12 supplements Smoking Pregnancy or lactation

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients, after stratification based on age and sex, are randomly allocated to either a vitamins B6, B9, B12 or placebo group by block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Supplement and placebo tablets are packaged by a person who hasn't any involvement in the study. The packages are completely identical, each package is coded to A and B so the researchers, distributor, and participants are kept blinded to the allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Central building of Shiraz University of Medical Sciences, Infront of Felestin St., Zand St.

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2018-07-03, 1397/04/12

Ethics committee reference number
IR. SUMS.REC.1397.325

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

2

Description of health condition studied
Overweight and obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Homocystein
Timepoint
At baseline and the end of week 8
Method of measurement
Colorimetric method

Secondary outcomes

1

Description
Alanine transaminase (ALT)
Timepoint
at baseline and the end of week 8
Method of measurement
Colorimetric method

2

Description
Aspartate transaminase (AST)
Timepoint
at baseline and the end of week 8
Method of measurement
Colorimetric method

3

Description
High sensitivity C-reactive protein (hs-CRP)
Timepoint
at baseline and the end of week 8
Method of measurement
ELISA

4

Description
Malondialdehyde (MDA)
Timepoint
at baseline and the end of week 8
Method of measurement
Thiobarbituric acid method

5

Description
Fasting blood sugar (FBS)
Timepoint
at baseline and the end of week 8
Method of measurement
Enzymatic method

6

Description
Insulin
Timepoint
at baseline and the end of week 8
Method of measurement
ELISA

7

Description
Triglyceride (TG)
Timepoint
at baseline and the end of week 8
Method of measurement
Enzymatic method

8

Description
Total cholesterol (TC)
Timepoint
at baseline and the end of week 8
Method of measurement
Enzymatic method

9

Description
High-density lipoprotein (HDL)
Timepoint
at baseline and the end of week 8
Method of measurement
Enzymatic method

10

Description
Low-density lipoprotein (LDL)
Timepoint
at baseline and the end of week 8
Method of measurement
Enzymatic method

11

Description
Serum vitamin B9
Timepoint
at baseline and the end of week 8
Method of measurement
ELISA

12

Description
Serum vitamin B12
Timepoint
at baseline and the end of week 8
Method of measurement
ELISA

13

Description
Anthropometric parameters
Timepoint
at baseline and the end of week 8
Method of measurement
Balance, meter

14

Description
Food intake
Timepoint
at baseline and the end of week 8
Method of measurement
3-day food records

15

Description
Physical activity level
Timepoint
at baseline and the end of week 8
Method of measurement
International physical activity questionnaire short form (IPAQ-SF)

Intervention groups

1

Description
Intervention group: Tablet containing vitamin B6 (20mg), vitamin B9 (1mg), vitamin B12 (50µg) once aday for 8 weeks
Category
Treatment - Other

2

Description
Control group: Tablet containing maltodextrin once aday for 8 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahary Polyclinic
Full name of responsible person
Dr. Ali Jangju
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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7th floor, Central Building of Shiraz University of Medical sciences, Zand Blvd., Shiraz, Iran
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hassan Eftekhari
Position
Professor
Latest degree
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Other areas of specialty/work
Nutrition
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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Nazanin Mohammadipoor

Position

Msc Student of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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