

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 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 don't 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, vegetarian 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

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

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

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Razi s.t, Shiraz, Iran.

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Eftekhari

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

Shiraz University of Medical Sciences

Full name of responsible person

Nazanin Mohammadipoor

Position

Msc Student of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

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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