

# 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)

###### Phone

+98 21 3751 0016

###### Email address

nazanin.mohammadipoor70@gmail.com

##### 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 /m<sup>2</sup> 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

Namazi Square

##### City

Shiraz

##### Province

Fars

##### Postal code

۷۱۳۳۶ - ۷۱۳۴۸

##### Phone

+98 71 3612 1000

##### Email

info@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

7th floor, Central Building of Shiraz University of Medical sciences, Zand Blvd., Shiraz, Iran

##### City

shiraz

##### Province

Fars

##### Postal code

۷۱۳۳۶ - ۷۱۳۴۸

##### Email

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

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7153675541

##### Phone

+98 71372510015

**Email**

h\_eftekhari@yahoo.com

## Person responsible for scientific 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

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h\_eftekhari@yahoo.com

## 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**

Nutrition

**Street address**

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

**City**

Shiraz

**Province**

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**Postal code**

7153675541

**Phone**

+98 71372510015

**Email**

nazanin.mohammadipoor70@gmail.com

## 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