

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patient with nonalcoholic fatty liver disease

#### Protocol summary

##### Summary

The main purpose: the effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patients with nonalcoholic fatty liver randomized, double-blind, placebo-controlled inclusion criteria: age 18 years and above; Concentrations of liver enzymes ALT and AST greater than 1.5 times normal; Evidence of nonalcoholic steatohepatitis in Fibroscan Exclusion criteria: Not continue to cooperation; Those less than 10% supplement at the end of the sixth and twelfth week consume. Summary of the project: In this study, patients with non-alcoholic fatty liver if they wish to participate in the study consent form them to be taken. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, inflammatory factors and other serum biochemical parameters and kept in the freezer. Participants randomly using the divided randomly classified into two groups: supplement and placebo group. Patients group supplement received daily 2 grams of citrulline for three months and Patients in the control group received placebo daily 2 grams. At the end of the third months, anthropometric, dietary recall and serum is taken and with fibroscan, changes in the degree of hepatic steatosis recorded

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201703194010N18**

Registration date: **2017-10-13, 1396/07/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-13, 1396/07/21

##### Registrant information

###### Name

Azita Hekmatdoost

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2293 0824

###### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

National Nutrition and Food Technology Research  
Institute Iran Iran University of Medical Sciences of  
Colorectal Research Center

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-06-05, 1396/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patient with nonalcoholic fatty liver disease

##### Public title

investigate effect of citrulline in the treatment of non-

alcoholic fatty liver

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria for the study: Age 18 and older; Concentrations of liver enzymes ALT and AST greater than 1.5 times normal; Evidence of nonalcoholic steatohepatitis in Fibroscan (Controlled Attenuation Parameter (CAP) score > 263); Have not a history of consumption alcohol more than 10 milligrams of per day for women and more than 20 mg per day for men; Not consume any dietary supplement in the past three months not consume any hepatotoxic drugs such as phenytoin, lithium Exclusion criteria: Not continue to cooperation; Biliary diseases; autoimmune and cancer and inherited disorders affecting liver during the study; Those less than 10% supplement at the end of the sixth and twelfth week consume.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sci

##### Street address

West arghavan, Sanaat square, Farahzadi boulevard, Shahrake gharb

##### City

Tehran

##### Postal code

#### Approval date

2017-03-06, 1395/12/16

#### Ethics committee reference number

IR.SBMU.nnftri.13950107

## Health conditions studied

### 1

#### Description of health condition studied

non alcoholic fatty liver disease

#### ICD-10 code

(K75.8)

#### ICD-10 code description

Other specified inflammatory liver diseases

## Primary outcomes

### 1

#### Description

LDL-C

#### Timepoint

Being and end of intervention

#### Method of measurement

Enzymatic methods using kits

### 2

#### Description

HDL-C

#### Timepoint

Being and end of intervention

#### Method of measurement

Enzymatic methods using kits

### 3

#### Description

TG

#### Timepoint

Being and end of intervention

#### Method of measurement

Enzymatic methods using kits

### 4

#### Description

total Cholesterol

#### Timepoint

Being and end of intervention

#### Method of measurement

Enzymatic methods using kits

### 5

#### Description

FBS

#### Timepoint

Being and end of intervention

#### Method of measurement

Enzymatic methods using kits

### 6

#### Description

Fasting insulin

#### Timepoint

Being and end of intervention  
**Method of measurement**  
Radioimmunoassay µU/mL

## 7

**Description**  
AST

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Enzymatic methods using kits

## 8

**Description**  
ALT

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Enzymatic methods using kits µg/m

## 9

**Description**  
HOMA

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Calculation

## 10

**Description**  
TNF-α

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Elisa Pg/dl

## 11

**Description**  
IL\_6

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Elisa Pg/dl

## 12

**Description**  
steatosis

**Timepoint**  
Being and end of intervention

**Method of measurement**  
Ultrasonography Grade 0: absence of steatosis grade 1:  
mild steatosis grade 2: moderate steatosis grade 3:  
severe steatosis

## **Secondary outcomes**

## 1

**Description**  
Total energy intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire Kcal per day

## 2

**Description**  
Carbohydrate intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 3

**Description**  
Protein intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 4

**Description**  
total fat intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 5

**Description**  
SAFA intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 6

**Description**  
PUFA intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 7

**Description**  
MUFA intake

**Timepoint**  
Beginning and end of intervention

**Method of measurement**  
questionnaire gram per day

## 8

### **Description**

total fiber intake

### **Timepoint**

Beginning and end of intervention

### **Method of measurement**

questionnaire gram per day

## **Intervention groups**

### 1

### **Description**

intervention group:2 gram citrulline per day for three months

### **Category**

Treatment - Other

### 2

### **Description**

placebo group:2 gram starche per day for three months

### **Category**

Other

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Rasool Akram Hospital

#### **Full name of responsible person**

Zahra Darabi

#### **Street address**

#### **City**

Tehran

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences,  
National Nutrition and Food Technology Research

#### **Full name of responsible person**

Azita Hekmatdoost

#### **Street address**

West arghavan, Sanaat square, Farahzadi boulevard,  
Shahrake gharb

#### **City**

tehran

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shahid Beheshti University of Medical Sciences, National  
Nutrition and Food Technology Research

### **Proportion provided by this source**

### **Public or private sector**

*empty*

### **Domestic or foreign origin**

*empty*

### **Category of foreign source of funding**

*empty*

### **Country of origin**

### **Type of organization providing the funding**

*empty*

### 2

### **Sponsor**

#### **Name of organization / entity**

Colorectal Research Center,IRAN University of Medical  
Sciences

#### **Full name of responsible person**

shahram agah

#### **Street address**

nyayesh street.rasol akram,hospital

#### **City**

tehran

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Colorectal Research Center,IRAN University of Medical  
Sciences

### **Proportion provided by this source**

### **Public or private sector**

*empty*

### **Domestic or foreign origin**

*empty*

### **Category of foreign source of funding**

*empty*

### **Country of origin**

### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

### **Contact**

#### **Name of organization / entity**

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

#### **Full name of responsible person**

Azita Hekmatdoust

#### **Position**

Nutritionist

#### **Other areas of specialty/work**

#### **Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Postal code****Phone**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Zahra Darabi

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

+98 21 8888 8781

**Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*