# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Effects of soy milk consumption on liver enzymes,lipid profile,glycemic status, markers of inflammation and oxidative stress and hepatic steatosis in non-alcoholic fatty liver patients.

## Protocol summary


**Summary**

Non-alcoholic fatty liver disease (NAFLD)is the most common liver disease. Diet plays an essential role in the management of disease. Recently, antioxidant-rich food sources such as soy products have gain a great interest in improvement of NAFLD. However, up to now, no study has investigated the effect of soy milk consumption on NAFLD. Therefore, the aim of this study is to assess the effects of soy milk consumption on metabolic and inflammatory status as well liver steatosis in NAFLD patients. In this randomized clinical trial study,70 patients aged 18 to 60 years will randomly assigned to intervention or control group. Since this study is a dietary intervention, there is no blinding. Both two group follow a 500-calorie deficit diet for 8 weeks. In intervention group, one glass of soy milk ( 240 cc ) is replaced with one serving of both starches and fats groups based on dietary exchange list. While, patients in the control group not allowed to consume any forms of soy products or isoflavone supplements during the study.All laboratory test including liver enzymes, lipid profile, markers of oxidative stress and inflammation, glycemic status, in addition hepatic steatosis, blood pressure and anthropometric indices will be measured at baseline and week 8 of the study. Also, the dietary intakes and physical activity will be measured at baseline and end of the study.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201701162709N40**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-02-19, 1395/12/01

**Registrant information**

**Name**
Farzad Shidfar
**Name of organization / entity**
Iran University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research, Iran University of Medical Sciences.

**Expected recruitment start date**

2017-02-23, 1395/12/05

**Expected recruitment end date**

2018-02-24, 1396/12/05

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of soy milk consumption on liver enzymes,lipid profile,glycemic status, markers of inflammation and oxidative stress and hepatic steatosis in non-alcoholic fatty liver patients.

**Public title**

Effect of soy milk consumption on non-alcoholic fatty liver disease.

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria : patient aged 18- 60 y ; diagnosis of NAFLD in accordance to American Gastroenterological Association guidelines as follows: a) hepatic steatosis confirmed by ultrasonography , b) there are no cause for secondary steatosis such as alcohol consumption, hereditary disorders( e.g. hemochromatosis,wilson's disease) ,autoimmune diseaseses ,hepatotoxic drugs (e.g. methotrexate , amiodaron, tamoxifen, corticosteroids, valproate and anti-viral drugs) and chronic hepatitis C ; Absence of any other co-disorders including but not limited to other chronic liver diseases (hepatitis), cirrhosis, celiac, diabetes, thyroid disorders, breast cysts, as well as cardiovascular, renal, respiratory ,inflammatory and autoimmune diseases ; Absence of cancer or a history of cancer in patient and his/her first-degree relatives ; BMI of 25 to 40 (kg/m2) ; having no allergy to soy milk ; consuming no nutritional supplements during the last two months ; Taking no anti-inflammatory drugs; hasn't any history of drug abuse and smoking; no pregnancy or lactation ; willingness to participate and sign an informed written consent.
Exclusion criteria: Lack of willingness to be a study participants during the study ; allergy or intolerance to soy milk during the study ; Lack of adherence to soy milk consumption ; existence of medical conditions that require special treatments during the study .

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway.

**City**

Tehran

**Postal code**

1449614535

**Approval date**

2017-01-16, 1395/10/27

**Ethics committee reference number**

IR.IUMS.REC 1395.9411468003

## 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**

Liver enzymes (ALT,AST,ALP,GGT)

**Timepoint**

before the experiment and 8 weeks after intervention

**Method of measurement**

colorimetery

### 2

**Description**

Lipid profile (TC,TG,HDL-C)

**Timepoint**

before the experiment and 8 weeks after intervention

**Method of measurement**

enzymatic method

### 3

**Description**

serum hs-CRP

**Timepoint**

before the experiment and 8 weeks after intervention

**Method of measurement**

immunoturbidimetry

### 4

**Description**

Insulin sensitivity index (QUICKI)

**Timepoint**

before the experiment and 8 weeks after intervention

**Method of measurement**

formula

**5**

**Description**
Fasting blood sugar
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
enzymatic method

**6**

**Description**
serum Insulin
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
Chemiluminescence immunoassay

**7**

**Description**
Malondialdehyde
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
colorimetery

**8**

**Description**
Insulin resistance (HOMA-IR)
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
formula

**9**

**Description**
the β-cell function ( % HOMA-β )
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
formula

**10**

**Description**
LDL-C
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
formula

**11**

**Description**
hepatic steatosis
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
ultrasonography

## Secondary outcomes

**1**

**Description**
Systolic blood pressure
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
mercury sphygmomanometer

**2**

**Description**
Diastolic blood pressure
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
mercury sphygmomanometer

**3**

**Description**
Plasma fibrinogen
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
clauss method

**4**

**Description**
weight
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
Seca scale

**5**

**Description**
waist circumference
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
elastic tape

**6**

**Description**
Body mass index
**Timepoint**
before the experiment and 8 weeks after intervention
**Method of measurement**
formula

## Intervention groups

**1**

**Description**
Control group ) following a 500- calorie deficit diet plan with macronutrients composition of 30 % fat , 15 %

protein and 55 % carbohydrate

**Category**

Other

**2**

**Description**

Intervention group) The calorie and macronutrients composition of diet is equal to the control group.In this group, one glass of soy milk ( 240 cc ) is replaced with one serving of both starches and fats groups

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Rasoul Akram Hospital, Iran University of Medical Sciences

**Full name of responsible person**

Dr.Shahram Agah

**Street address**

Rasoul Akram Hospital, Niyayesh St, Sattarkhan Ave.

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Javad Moosavi

**Street address**

7th Floor, , Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St , Sattarkhan Ave, Tehran, Iran.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Iran University of Medical Sciences

**Proportion provided by this source**

100

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr.Farzad Shidfar

**Position**

Professor

**Other areas of specialty/work**

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## 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*