

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 gained 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 as liver steatosis in NAFLD patients. In this randomized clinical trial study, 70 patients aged 18 to 60 years will be randomly assigned to intervention or control group. Since this study is a dietary intervention, there is no blinding. Both two groups follow a 500-calorie deficit diet for 8 weeks. In the 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 are not allowed to consume any forms of soy products or isoflavone supplements during the study. All laboratory tests including liver enzymes, lipid profile, markers of oxidative stress and inflammation, glycemic status, in addition to 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

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Name of organization / entity

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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	
<u>1</u>	
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	
<u>1</u>	
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	
<u>1</u>	
Description	Liver enzymes (ALT,AST,ALP,GGT)
Timepoint	before the experiment and 8 weeks after intervention
Method of measurement	colorimetry
<u>2</u>	
Description	Lipid profile (TC,TG,HDL-C)
Timepoint	before the experiment and 8 weeks after intervention
Method of measurement	enzymatic method
<u>3</u>	
Description	serum hs-CRP
Timepoint	before the experiment and 8 weeks after intervention
Method of measurement	immunoturbidimetry
<u>4</u>	
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

colorimetry

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

claus 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

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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