Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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

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Full name of responsible person

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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