Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of soy isoflavones on metabolic profile, liver enzymes, hepatic fibrosis, inflammatory markers and total antioxidant capacity in patients with non-alcoholic fatty liver disease, double blind randomized clinical trial

Protocol summary

Study aim
Determining the effects of soy isoflavones on metabolic profile, the level of liver enzymes, liver fibrosis, inflammatory factors and total antioxidant capacity in patients with non-alcoholic fatty liver disease.

Design
Two arm parallel groups randomised trial, double-blind, on 50 patients.

Settings and conduct
Patients are randomly assigned to two groups including Soyagol supplement or placebo for twelve weeks. The sampling location is Tehran. In order to carry out this research in a double-blind manner, at the time of starting the study, the cans containing soy isoflavone supplement or placebo are coded as A and B by a third party (a person other than the researcher) so that the researcher and patients will not know the type of the supplement received by each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The concentration of liver enzymes, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) shall be more than 1.5 fold of the maximum normal level. With evidence of non-alcoholic fatty liver in fibroscan (CAP score>260) Without a history of alcohol consumption or consuming alcohol less than 10 and 20 grams per day in women and men, respectively. Non-inclusion criteria: Pregnancy and breastfeeding History of breast cancer Consuming levothyroxine, warfarin and iron History of allergy to soy and its products

Intervention groups
Soy isoflavone group and placebo group

Main outcome variables
The level of liver enzymes, liver fibrosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220801055597N1**
Registration date: **2022-09-20, 1401/06/29**
Registration timing: **prospective**

Last update: **2022-09-20, 1401/06/29**
Update count: **0**

Registration date
2022-09-20, 1401/06/29

Registrant information

Name
Asal Neshatbini Tehrani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8608 1522

Email address
asalnt@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-24, 1401/07/02

Expected recruitment end date
2023-02-04, 1401/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of soy isoflavones on metabolic profile, liver enzymes, hepatic fibrosis, inflammatory markers and total antioxidant capacity in patients with non-alcoholic fatty liver disease, double blind randomized clinical trial

Public title
Effect of soy isoflavones in non alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18-75 years old Willingness to participate in study The concentration of liver enzymes, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) shall be more than 1.5 fold of the maximum normal level. With evidence of non alcoholic fatty liver disease in Fibroscan (CAP score>260) Without a history of alcohol consumption or consuming alcohol less than 10 grams per day in women and less than 20 grams per day in men. Not taking drugs that affect blood lipids, blood sugar and blood pressure, vitamin E and ursodioxycholic acid (UDCA) and hepatotoxic drugs such as phenytoin, amoxifen, lithium, methotrexate, amiodarone, tamoxifen, corticosteroids, valproate, antiviral drugs, etc. .. Without a history of other diseases, chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, autoimmune diseases, cancer and hereditary disorders affecting the liver (iron or copper storage disease , etc.). Without a history of celiac disease, diabetes, cardiovascular diseases, lung disease, digestive disease affecting food absorption and kidney disease. Without a history of weight loss surgery in the past year or a history of adherence to a weight loss diet in the last 6 months Without a history of thyroid disorder Not taking fiber and soy supplements in the last 3 months Without a history of smoking (cigarettes and other tobacco products) Not regular consumption of soy or soy products in the diet (regular consumption means: consuming more than 30 grams (more than 2 tablespoons) per month) Without a history of liver cirrhosis or not being classified in F4 group

Exclusion criteria:
Pregnancy and breastfeeding History of breast cancer Consuming levothyroxine, warfarin and iron History of allergy to soy and its products

Age
From **18 years** old to **75 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
In this study, patients are randomly assigned to either soy isoflavone or placebo groups. Stratified Blocked Randomization method is used to randomly assign patients to two groups. The size of the blocks will be 4 and matching will be done based on gender and menopause status in women.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study. For this purpose, at the start of the study, the cans containing soy isoflavone supplements or placebo are coded as A and B by a third party (a person other than the researchers) so that the researchers and patients do not know the type of supplements received by each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Unit 7, No 16, Corner of Madaran St, Nezamiye Ganjavi St, Abbaspour Sq, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1434793388

Approval date
2022-08-01, 1401/05/10

Ethics committee reference number
IR.AJUMS.REC.1401.155

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
The level of liver enzymes, the level of liver fibrosis
Timepoint
At the beginning of the study and at the end of the twelfth week
Method of measurement
Using a blood test for measuring the level of liver enzymes, using a Fibroscan device for measuring the level of liver fibrosis

Secondary outcomes

1

Description
Metabolic profile (height, weight, waist circumference, hip circumference, waist to hip ratio, BMI), systolic and diastolic blood pressure, total cholesterol level, LDL, HDL, triglyceride, glucose and insulin concentration, insulin resistance (HOMA) -IR), insulin sensitivity
Timepoint
At the beginning and at the end of the study
Method of measurement
Using a tape meter to measure height, waist circumference and hip circumference, using a digital scale to measure weight, using a digital sphygmomanometer to measure blood pressure and using a blood test to measure blood fat and blood sugar .

2

Description
FGF-21 and Fetuin A hepatokines
Timepoint
At the beginning and at the end of the study
Method of measurement
Blood test

3

Description
Serum total antioxidant capacity
Timepoint
At the beginning and at the end of the study
Method of measurement
Using blood test

Intervention groups

1

Description
Intervention group: Patients in the soy isoflavone group will receive two Soyagol tablets per day with breakfast and dinner for 12 weeks. Soyagol supplement in each tablet contains 50 mg of soy isoflavones, of which 20 to 27 mg is genistein and the rest are other soy isoflavones. This supplement is produced and supplied by Gol Daru herbal pharmaceutical company located in Isfahan city ,Iran.
Category
Treatment - Drugs

2

Description
Control group: Patients in the placebo group will receive two placebo tablets per day containing starch , which are completely similar in shape and size to soy isoflavone supplements and are produced by the same pharmaceutical company (Gol Daru) that supplies Soygol supplements.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr. Azita Hekmatdoust
Street address
Unit 7, No16, Corner of Madaran St, Nezamiye Ganjavi St, Abbaspour Sq, Teran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Bizhan Helli
Street address
Unit 7, No 16, Corner of Madaran St, Nezamiye Ganjavi St, Abbaspour Sq, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
60
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
Ahvaz University of Medical Sciences
Full name of responsible person
Asal Neshatbini Tehrani
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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
Yes - There is 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
Title and more details about the data/document

The clinical reports of the study will be shared after the completion of the study

When the data will become available and for how long

3/3/2023-2/5/2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To conduct more studies in the same field

From where data/document is obtainable

Email the person who is in charge of this study (asalnt@yahoo.com)

What processes are involved for a request to access data/document

It takes at least a month

Comments