

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

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asall.tehranii@gmail.com

**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 scientific inquiries

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## Person responsible for updating data

### Contact

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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**