

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of genistein supplementation on inflammatory and oxidative indices and lipid profile in non-alcoholic fatty liver patients

Protocol summary

Summary

The aim of this study is to assess the effect of genistein supplementation on inflammatory and oxidative indices and lipid profile in non alcoholic fatty liver patients. This randomized, double-blind, placebo-controlled will be single center study. This study is in phase 3 of clinical trial. Inclusion criteria: adult volunteers between 18 and 70 whom their fatty liver were confirmed by ultrasonography and don't have any Acute or chronic disease of the liver or bile ducts will be recruited. Exclusion criteria: severe weight loss or gain, pregnancy, ALT serum level 10 times more than normal range during study. Patients will receive 250 mg genistein or placebo once a day for 8 weeks. Patients will have a pre and post treatment laboratory evaluation including measurements of serum AST, ALT, TNF- α , IL-6, triglyceride, total cholesterol, LDL, HDL and amount of hepatic steatosis (by fibroscan), waist circumference, weight and height.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312132480N5**
Registration date: **2015-07-11, 1394/04/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shiraz University Of Medical Sciences

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2015-11-06, 1394/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of genistein supplementation on inflammatory and oxidative indices and lipid profile in non-alcoholic fatty liver patients

Public title

Treatment of non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Volunteers whom their fatty liver were confirmed by ultrasonography; Don't have any Acute or chronic disease of the liver or bile ducts Exclusion criteria: Severe weight loss or gain; Pregnancy; ALT serum level 10 times more than normal range.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization carry out by simple randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Of Medical Sciences

Street address

Shiraz University of Medical Sciences main building,
Zand St, In Front Of Felestin St

City

Shiraz

Postal code

14336 - 71348

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SUMS.REC.1394.42

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

TNF- alpha

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

2

Description

IL-6

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

3

Description

ALT

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

4

Description

AST

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

5

Description

HDL

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

6

Description

LDL

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

7

Description

Total cholestrol

Timepoint

Before intervention and two months after intervention
inception

Method of measurement

By serum analysis

8

Description

Triglyceride

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By serum analysis

9

Description

Malondialdehyde

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By serum analysis

10

Description

Liver steatosis

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By fibroscan device

Secondary outcomes

1

Description

Waist circumference

Timepoint

Before and two months after intervention inception

Method of measurement

By tapeline in cm

2

Description

Waist circumference

Timepoint

Before and two months after intervention inception

Method of measurement

By scale in KG

Intervention groups

1

Description

Intervention group: 250 mg genistein as capsule once per day for 8 weeks manufacture company: BOC SCI

Category

Treatment - Drugs

2

Description

Control group: wheat starch in capsule once a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Sasan Amanat

Street address

Next to the Medicine Faculty, Karimkhan Zand Blvd

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th floor, Shiraz University Of Medical Sciences main building, next to Geneva Cross, Zand st

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sasan Amanat

Position

Msc student of Nutrition

Other areas of specialty/work

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Web page address**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