Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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

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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 cholesetrol
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 weeksmanufacture 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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Person responsible for scientific inquiries

Contact
Name of organization / entity
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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