Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Sep 2026

The effect of genistein supplementation on glycemic state, insulin resistance and adipose tissue in non alcoholic fatty liver patients

Protocol summary

Summary

The aim of this study is to assess the effect of genistein supplementation on glycemic state, insulin resistance and adipose tissue 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. 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 is 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 FBS, insulin, HOMA-IR and body fat mass (by BIA), waist circumference, weight and height.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506222480N6**
Registration date: **2015-07-12, 1394/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-12, 1394/04/21

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

Shiraz University Of Medical Scienses

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2015-11-05, 1394/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of genistein supplementation on glycemic state, insulin resistance and adipose tissue 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

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

City

Shiraz

Postal code

7134814336

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SUMS.REC.1394.43

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

Insulin

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By serum analysis

2

Description

FBS

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By serum analysis

3

Description

Fat mass

Timepoint

Before intervention and two months after intervention inception

Method of measurement

By BIA device

Secondary outcomes

1

Description

HOMA-IR

Timepoint

Before and two months after intervention inception

Method of measurement

Calculate by HOMA index equation

Intervention groups

1

Description

wheat starch in capsule once a day for 8 weeks

Category

Placebo

2

Description

250 mg genistein as capsule once per day for 8 weeks

Category

Treatment - Drugs

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

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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Dr. Seyed Basir Hashemi
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7th floor, Shiraz University Of Medical Sciences central 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

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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