

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of licorice root on metabolic factors, hepatic enzymes, hepatic steatosis, and oxidative stress in obese women with nonalcoholic fatty liver disease

Protocol summary

Study aim

The goal of this study was to assess effect of licorice root supplementation on lipid profile, glycemia profile, hepatic enzymes, hepatic steatosis, and oxidative stress of nonalcoholic fatty liver disease.

Design

A randomized, placebo-controlled, double-blind clinical trial

Settings and conduct

In this study 60 women with NAFLD, aged 18 _ 65, and body mass index > 25, were recruited from Shahid motahari clinic in Shiraz, Iran. Patients were randomly allocated in ti licorice and control groups by randomization. Both the researchers and participants were blinded throughout the study until the end of statistical analysis. All data of anthropometric measurements, and laboratory tests were collected at baseline and after intervention. All patients were advised to perform physical activity and weight loss diet.

Participants/Inclusion and exclusion criteria

Women with NAFLD, aged 18 to 65 years, BMI > 25 and fatty liver in sonography

Intervention groups

Licorice group and control group Intake of 1000 mg licorice root extract powder in licorice group Intake of 1000 mg maltidextrin in control group

Main outcome variables

ALT, AST, GGT, FBS, insulin resistance, serum insulin, LDL, HDL, Ttal cholesterol, Triglycerid, Liver steatosis, Wheight and BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200903048603N1**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **retrospective**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Pouya Rostamizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 0111

Email address

pouyarostamizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2020-01-30, 1398/11/10

Scientific title

Effects of licorice root on metabolic factors, hepatic enzymes, hepatic steatosis, and oxidative stress in obese women with nonalcoholic fatty liver disease

Public title

"Effect of Licorice in treatment of Nonalcoholic Fatty Liver Disease"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of acute or chronic Liver disease
Lack of using of Tobacco or alcohol
Lack of cardiovascular diseases, and Hypertension
Lack of Diabetes Mellitus, Kidney diseases, Malignancy, Viral Hepatitis, Wilson disease
Hemochromatosis, Cystic fibrosis and Autoimmune diseases
Lack of using of any approved therapies known to have potential benefit in NAFLD control within the previous 3 months
Lack of using of Hepatotoxic drugs within the past 6 months

Exclusion criteria:

Lack of Fatty Liver in Ultrasonography

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by computer randomization method using www.randomization.com Double_blind

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind

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, Zand Blvd,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶- ۷۱۳۴۸

Approval date

2019-06-05, 1398/03/15

Ethics committee reference number

IR.SUMS.REC.1398.891

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver steatosis

Timepoint

Previous of intervention and 3 months after of initiating of study

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Malondialdehyde

Timepoint

Previous of intervention and 3 months after of initiating of study

Method of measurement

Analysis of serum samples

2

Description

Alanine aminotransferase

Timepoint

Previous of intervention and 3 months after initiating study

Method of measurement

Analysis of serum samples

3

Description

Aspartate aminotransferase

Timepoint

Previous of intervention and 3 months after of initiating study

Method of measurement

Analysis of serum samples

4

Description

Gama glutamyl transpeptidase

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Analysis os serum samples

5

Description

Lipid profile

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Analysis of serum samples

6

Description

Fasting blood sugar

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Analysis of serum samples

7

Description

Serum insulin

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Analysis of serum samples

8

Description

HOMA- IR

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

(serum insulin × Fasting blood sugar) ÷ 405

9

Description

Wheight

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Using scale (kg)

10

Description

BMI (Body mass index)

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Wheight(kg) ÷ (Height (m) × Height (m))

11

Description

Liver steatosis

Timepoint

Previous of intervention and 3 months after initiating of study

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: Licorice root powder 1000 mg / day

Category

Treatment - Drugs

2

Description

Control group: Maltodextrin 1000 mg / day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid motahari clinic

Full name of responsible person

Dr Zohreh Mazloom

Street address

Shahid Motahari clinic, Zand Blvd, Nemazi sqr,,
Shiraz, Iran

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Phone

+98 71 3725 1007

Email

Zohreh.mazloom@gmail.com

2

Recruitment center

Name of recruitment center

Imam reza clinic

Full name of responsible person

Dr Zohreh mazloom

Street address

Imam reza clinic, Zand Blvd, Nemazi Sqr, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younos Ghasemi

Street address

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Vcrdep@sums.ac.ir

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

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

Shiraz University of Medical Sciences

Full name of responsible person

Pouya Rostamizadeh

Position

Master of Science(MSc) of Nutrition Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Razi Blvd,
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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Mazloom

Position

Professor of nutrition sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Pouya Rostamizadeh

Position

Master of Sciences (MSc) of Nutrition Sciences

Latest degree

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Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Nonexistence more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available