

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Aug 2026

Comparison of the efficacy of oral Trigonella foenum-graecum seed extract and placebo in the treatment of none alcoholic fatty liver disease

Protocol summary

Summary

This study design to examine performance of trigonella foenum-graecum in treatment of non-alcoholic fatty liver disease. Patients 18-70 year old with the levels of ALT and AST greater than 1.5 and less than 10 times normal level, and ultrasound evidence confirm fatty liver disease include in study. Patients with alcohol consumption, other liver disease and taking medications that cause liver injury, exclude. Base on inclusion and exclusion criteria, 50 patients select and then randomize into intervention and control groups. Control group, in addition to diet and exercise recommendations take placebo capsules for 3 months. Intervention group, in addition to diet and exercise recommendations, use capsules containing hydro-alcoholic extract of fenugreek 1g/d for 3 months. At baseline and 6 and 12 weeks after intervention, we measure FBS, insulin, insulin resistance, Albumin, Aspartate transaminase, Alanine Aminotransferase, Alkaline phosphatase, Total bilirubin, Direct bilirubin, HbA1c, total cholesterol, LDL, HDL, TG, High sensitivity C reactive protein and Creatinine. At baseline and 12 weeks after intervention fibroscan perform to evaluate the amount of fat in liver. In order to decrease bias, patient, physician who performs fibroscan and the person analyzing the data are blind to group drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102015083N1**

Registration date: **2014-09-01, 1393/06/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-01, 1393/06/10

Registrant information

Name

Amir Hossein Babaei

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2016-01-19, 1394/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral Trigonella foenum-graecum seed extract and placebo in the treatment of none alcoholic fatty liver disease

Public title

Effect of Fenugreek in treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the level of ALT and AST greater than 1.5 and less than 10 times normal level; Ultrasound

evidence confirm fatty liver disease; age between 18-70 years old; negative pregnancy test for women in reproductive age (up to two weeks prior to the study); negative for hepatitis B and C; BMI: 18.5 to 40; sign the consent form. Exclusion criteria: history of more than one unit of alcohol consumption (one value for the Spirits (vodka; whiskey); Wine and Beer are respectively 30-45 cc; 120-150 cc and 360 cc.); fatty liver controller medications; Glucose lowering drugs; Cholesterol lowering drugs; Hypotensive drugs; consumption of vitamin E; taking coenzyme Q10; administration of corticosteroids & glucocorticoids; thyroxin administration; administration of drugs that cause fatty liver; diabetes (type 1 and 2); history of cancer in the past; hepatocellular carcinoma; renal failure (creatinine > 1.5 x ULN); chronic pancreatitis; cirrhosis; uncontrolled hypertension (above 180 mm Hg systolic blood pressure); heart disease; autoimmune hepatitis; primary biliary cirrhosis; primary sclerosing cholangitis (alkaline phosphatase levels greater than 3 times normal); Wilson's disease; alpha-1 antitrypsin deficiency and coronary artery disease; symptoms of hypothyroidism; hyperthyroidism; disorders of the hypothalamic - pituitary; liver transplantation; pregnant or lactating women; and those who cannot use contraceptives.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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 - Zand street

City

Shiraz

Postal code

71345-1583

Approval date

2014-08-03, 1393/05/12

Ethics committee reference number

CT-P-9362-6352

Health conditions studied

1

Description of health condition studied

none alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver stiffness

Timepoint

At baseline and 12 weeks after intervention

Method of measurement

Fibro scan

2

Description

insulin resistance

Timepoint

At baseline and 6 and 12 weeks after intervention

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Control group, in addition to diet and exercise recommendations, use placebo capsules for 3 months.

Category

Placebo

2

Description

Intervention group, in addition to diet and exercise recommendations, use capsules containing fenugreek hydro alcoholic extract 1g / d for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Ali reza Taghavi

Street address

Namzi Sq.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali reza Taghavi

Street address

Karim Khan Street - Namazi Hospital-
Gastroenterology and Hepatology Research Center

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

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Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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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