Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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

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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 ot 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Karim Khan Street - Namazi Hospital- Gastroenterology and Hepatology Research Center
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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