Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Investigation of the Efficacy of Carom copticum on Fatty Liver Grade in Patients with Non-Alcoholic Fatty Liver

Protocol summary

Study aim

determine the effect of C.copticum on the improvement of fatty liver in patients with non-alcoholic fatty liver.

Design

In this research, 72 eligible patients with non-alcoholic Fatty liver referring to the gastroenterology clinic of Baghiyatallah Hospital were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

This is a double-blind clinical trial that was performed at gastroenterology clinic of Baghiyatallah Hospital in Tehran. The subjects of the study and the study monitoring committee blindness.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Non-Alcoholic fatty liver diagnosis of grades 1 to 3 based on sonography, age 18-60 years, person's willingness to participate in the study. Exit criteria: The patient's unwillingness to participate in the program; Hepatitis (cirrhosis, alcoholic liver disease, viral hepatitis and autoimmunity, cirrhosis, hereditary hemochromatosis, sclerosis, cholangitis, etc.); other serious illnesses (cancer, kidney failure Celiac and ...); pregnancy; lactation; use of drugs that affect liver tests over the past 2 months (statins, glitazones, chlorpropamizine, anabolic steroids, tionamides, vit.E, OCP, etc.); alcohol consumption. Also, if the liver enzymes increase during the course of the design and the need for treatment according to the expert opinion of the digestive tract, the patient will be excluded from the project.

Intervention groups

In this study, patients with fatty liver were randomly divided into two groups of 36 patients. The first group of carom copticum and the control group are given placebo. The drug and placebo are in capsules of 250 mg and twice a day after a meal with warm water for 8 weeks.

Main outcome variables

The study's outcomes include improving the degree of fatty liver in patients based on ultrasound, improving digestion of the stomach, and reducing liver enzymes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171102037178N2**
Registration date: **2018-03-11, 1396/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-11, 1396/12/20**
Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name

Rasoul Shafiezadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3436 9595

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-10, 1397/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Efficacy of Carom copticum on Fatty Liver Grade in Patients with Non-Alcoholic Fatty Liver

Public title

effect of C.copticum on non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of non-alcoholic fatty liver with grade 1 to 3 according to liver ultrasound The patient's willingness to participate in the plan Age of 18 to 60 years

Exclusion criteria:

Unwillingness to participate in the plan Disease of the liver Like: Hepatitis, Hemochromatosis, Cirrhosis Use of effective drugs on liver tests over the past 2 months People with heart failure or kidney disease or diabetes alcohol consumption Pregnancy or breastfeeding

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in this project fall into two groups of intervention and control by simple accident method. Individuals are divided into two intervention and control groups according to random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind clinical trial in which study subjects and the study monitoring committee study blindness.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Shahed University

Street address

Opposite of Imam Khomeiny shrine, Tehran-Qom Freeway, Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.Shahed.REC.1396.82

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease [NAFLD]

ICD-10 code

K76.0

ICD-10 code description

K76.0Fatty (change of) liver, not elsewhere classified Nonalcoholic fatty liver disease [NAFLD]

2

Description of health condition studied

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

grade of fatty liver in ultrasound

Timepoint

Evaluating the degree of fatty liver at the beginning of the study and three months after treatment

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" The prescribing of the food capsule

containing the fruit juice of Carum Copticum , on the basis of 4 grams of fruit , 3 times a day for eight consecutive weeks.

Category

Treatment - Drugs

2

Description

Control group: placebo plus routine care

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallah hospital؛ Gastroenterology clinic؛ Tehran

Full name of responsible person

Rasoul shafiezadeh

Street address

Baqiyatallah Hospital; Sheikh Bahaei Intersection; Mulla Sadra Street; Vank Square; Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra kiasalary

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Shahed University, Aftab City, Persian Gulf Highway

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Web page address

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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

Shahed University

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

Shahed University

Full name of responsible person

Rasoul shafiezadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available