

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the effect of Dva'-Albalgham ,on serum levels of liver enzymes in patients with NAFLD.

Protocol summary

Summary

The purpose of this study was to investigate the effect of a traditional medicine on the serum level of liver enzymes in patients with fatty liver disease. The drug is "Dava AL-balgham" that includes the equal proportions of Nigella Sativa ,Zataria Multiflora, Trachyspermum ammi, Pistacia lentiscus which is found in authentic texts of traditional medicine and the official authorities of the drug botanic and new papers on the effects of digestion and eliminating swollen and anti-inflammatory drugs. Anti Atherogenic, have antioxidants. This project is done at the traditional medicine Clinic of the Qom University of Medical Sciences and a gastroenterologist's office. Participants who are satisfied with participation in the ultrasound diagnosis of Fatty Liver Disease and who have been tested for elevated liver enzymes have two A group of 50 patients and matched controls are randomly assigned a code that randomly receives a drug or placebo at two servings per each meal, and at the end of three months, liver enzymes, urea and creatinine levels , Ferritin, weight and ratio of waist circumference to hip and quality of life will be checked. Participants will be given a plan for modifying lifestyle guidelines Until the main treatment of fatty liver disease is not deprived.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073135415N1**
Registration date: **2017-09-17, 1396/06/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

Name

Fatemeh Tooiserkani

Name of organization / entity

Iranian Traditional Medicine of qom

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 7843

Email address

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Recruitment status

Recruitment complete

Funding source

The financial resources are through the university's research deputy.

Expected recruitment start date

2017-08-21, 1396/05/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Dva'-Albalgham ,on serum levels of liver enzymes in patients with NAFLD.

Public title

Assesment of "Dawa al-Blaghm" on liver enzymes in patients with fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Non-Alcohol-Fatty Liver Detection (NAFLD-Based Ultrasonography) 2- Serum Liver Enzyme Levels above Normal 3- Age between 18 and 65 years. 4-

Fill in the consent form for participation in the plan.
Exclusion criteria: 1. Patient's lack of consent to continue participating in the project. 2. Any allergy to the drug. 3. The occurrence of any new liver disease that requires the use of specific liver medicines. 4. Pregnancy.

Age

From **17 years** old to **64 years** old

Gender

Both

Phase

N/A

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

By using the available sampling method, individuals with entry and failure criteria will be included in the study, then treatments will be assigned based on random blocks of four. The blocks and its size and code of cure will be provided by a counselor to a person other than the medical, who measures the response of the patients. Blocks will be randomly selected. According to the estimated number of samples, 25 blocks of volume 4 will be used to select random blocks of dice throwing or Proc PLAN in SAS 9.2 software. Which is based on the treatments provided. In this way, the choice of treatment type, block selection and sequence of individuals in each block will also be random.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

Street address

University of Medical Sciences, Saheli street, Qom, Iran

City

Qom

Postal code**Approval date**

2017-07-04, 1396/04/13

Ethics committee reference number

IR.MUQ.REC.1396.44

Health conditions studied**1****Description of health condition studied**

Fatty liver disease

ICD-10 code

k76.0

ICD-10 code description

Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes**1****Description**

Ast

Timepoint

On arrival, three months after taking a medication or placebo

Method of measurement

U / L, Spectrophotometer

2**Description**

Alt

Timepoint

On arrival, three months after taking a medication or placebo

Method of measurement

U / L, Spectrophotometer

3**Description**

Alkp

Timepoint

On arrival, three months after taking a medication or placebo

Method of measurement

U / L, Spectrophotometer

Secondary outcomes**1****Description**

Crt

Timepoint

At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement

U / L, Spectrophotometer

2**Description**

BUN

Timepoint

At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
U / L, Spectrophotometer

3

Description
PT

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
U / L, Spectrophotometer

4

Description
PTT

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
U / L, Spectrophotometer

5

Description
INR

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
U / L, Spectrophotometer

6

Description
level of quality of life

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
Questionnaire 36 questions

7

Description
BMI

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
Weight/(height(meter))² Kg/m²

8

Description
WHR

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
Waist to hip circumference Cm/cm

9

Description
Blood pressure

Timepoint
At the beginning of the intervention, three months after taking the medication or placebo

Method of measurement
Mercury pressure meter mmHg

Intervention groups

1

Description
The case group receives Dava Al-balgham tablets two pills with each meal, for three months.

Category
Treatment - Drugs

2

Description
The control group receives cellulose tablets in two tablets each serving for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Gastroenterology and Traditional Medicine of Qom University of Medical Sciences, located i

Full name of responsible person

Fateme Tooiserkani

Street address

Faculty of Traditional Iranian Medicine, Third Floor, Faculty of Dentistry, Shahlahi St., Qom.

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

No. 83, Alley No.4, Alley 1.1, Safashahr sr. Qom.

City

Qom

Grant name

2647.3

Grant code / Reference number

2647.3

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Qom 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**

Faculty of Traditional Iranian Medicine Qom

Full name of responsible person

Hossein Moradi

Position

Professor of Iranian traditional medicine

Other areas of specialty/work**Street address**

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Full name of responsible person

Hossein moradi

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Faculty of traditional Medicine, Qom University of
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Full name of responsible person

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Position

Assistant of iranian traditional medicine

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Web page address**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