Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Nov 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

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Fatemeh Tooiserkani
Name of organization / entity
Iranian Traditional Medicine of qom
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Iran (Islamic Republic of)
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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 desease

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 presure
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.د
Grant code / Reference number
2647.د

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
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Hossein Moradi
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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