# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Oct 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
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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
**Full name of responsible person**
Hossein Moradi
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*