# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Nov 2026

## The effect of Zataria multiflora Boiss in the treatment of non alcoholic fatty liver disease

## Protocol summary

**Summary**

In this randomized double blind clinical trial a traditional drug (Shirazi thyme) is compared with placebo in the treatment of non alcoholic fatty liver disease. Of the patients referred to Shahid Motahari and Faghihi clinics in Shiraz we select 90 persons with NAFLD by inclusion criteria. We measure anthropometric and laboratory parameters including FBS, Insulin, liver enzymes, lipid profile, and grade in sonography before intervention and 90 days later. Patients are divided into two 45 persons groups. Intervention group in addition to diet and exercise recommendations receive capsules containing 700 mg Shirazi thyme powder bid for 90 days. Control group in addition to the same recommendations receive placebo capsules. Patients and physician are blind to intervention.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015120925447N1**
Registration date: **2016-10-16, 1395/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-10-16, 1395/07/25

**Registrant information**

**Name**

Nasrin dokht Zamani

**Name of organization / entity**

shiraz university of medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3635 8186

**Email address**

zamanina@sums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Shiraz University of Medical Sciences

**Expected recruitment start date**

2016-05-22, 1395/03/02

**Expected recruitment end date**

2017-03-22, 1396/01/02

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Zataria multiflora Boiss in the treatment of non alcoholic fatty liver disease

**Public title**

The effect of Shirazi thyme in the treatment of fatty liver

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: signed informed consent; age between 20 to 65 years old; BMI : 18 - 35; evidence of fatty liver in sonography; ALT equal or more than 45 in male and equal or more than 29 in female. Exclusion criteria: pregnancy; lactation; alcohol consumption; diabetes mellitus; history of allergic reaction to Thyme; acute or chronic hepatic disease; treated or untreated malignancy; consumption of hepatotoxic drugs during six months ago or less; consumption of drugs with effect on the biochemical markers of this study during three months ago or less; hyper or hypothyroidism; renal insufficiency (Cr > 1.5 ).

**Age**
From **20 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
**Street address**
Central building of Shiraz University of Medical Sciences, Zand blvd.
**City**
Shiraz
**Postal code**
**Approval date**
2016-02-21, 1394/12/02
**Ethics committee reference number**
IR.SUMS.REC.1394.199

## Health conditions studied

### 1

**Description of health condition studied**
Non alcoholic fatty liver
**ICD-10 code**
K 76.0
**ICD-10 code description**
Non alcoholic fatty liver disease

## Primary outcomes

### 1

**Description**
Alaninaminotransferase
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
Blood sampling

### 2

**Description**
Grade of fatty liver
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
Ultrasonography

## Secondary outcomes

### 1

**Description**
Blood pressure
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
By manometer according to mmHg

### 2

**Description**
Fasting blood sugar
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
Blood sampling

### 3

**Description**
Aspartateaminotransferase
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
Blood sampling

### 4

**Description**
Body mass index
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
Scale and measuring tape

### 5

**Description**
Waist circumference
**Timepoint**
Before intervention and three months after intervention
**Method of measurement**
By measuring tape

### 6

**Description**

Hip circumference

**Timepoint**

Before intervention and three months after intervention

**Method of measurement**

By measuring tape

**7**

**Description**

Insulin

**Timepoint**

Before intervention and three months after intervention

**Method of measurement**

Blood sampling

**8**

**Description**

Lipid profile

**Timepoint**

Before intervention and three months after intervention

**Method of measurement**

Blood sampling

## Intervention groups

**1**

**Description**

Intervention group : 700 mg (two 350 mg cap ) Shirazi thyme powder bid for 90 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group : 700 mg (two cap 350 mg ) wheat powder bid for 90 days

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Motahari cliinic

**Full name of responsible person**

Nasrin dokht Zamani

**Street address**

Motahari cliinic, Namazi square

**City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Faghihi clinic

**Full name of responsible person**

Nasrin Dokht Zamani

**Street address**

Faghihi clinic, Zand Blvd.

**City**

Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Basir Hashemi

**Street address**

Central building of Shiraz University of Medical Sciences, Zand blvd.

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, 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

**Contact**

**Name of organization / entity**

Faculty of Traditional Medicine, Shiraz University of Medical Sciences

**Full name of responsible person**

Nasrin Dokht Zamani

**Position**

MD, PhD student of traditonal medicine

**Other areas of specialty/work**

**Street address**

Seventh floor, Faculty of Medicine, Imam Hossein square, Zand boulevard

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Endocrine research center, Shiraz University of Medical Sciences

**Full name of responsible person**
Mesbah Shams

**Position**
Associate professor ( subspecialist in Endocrinology )

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Faculty of Traditional Medicine, Shiraz University of Medical Sciences

**Full name of responsible person**
Nasrin Dokht Zamani

**Position**
MD , PhD student of traditional medicine

**Other areas of specialty/work**

**Street address**
Seventh floor, Faculty of Medicine, Imam Hossein square, Zand boulevard

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Shiraz

**Postal code**

**Phone**
+98 71 3635 8186

**Fax**

**Email**
nzamani117@yahoo.com

**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*