

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 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
City
Shiraz
Postal code
Phone
+98 71 3635 8186
Fax
Email

nzamani117@yahoo.com

Web page address

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

Street address

Namazi hospital, Namazi square

City

Shiraz

Postal code

Phone

+98 71 3647 4316

Fax

Email

shams@sums.ac.ir

Web page address

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

City

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