

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Iranian traditional medicine-based diet on Non-alcoholic fatty liver (NAFLD)

Protocol summary

Summary

Purpose: This study is a randomized clinical trial that aims to evaluate and compare the conventional medicine diet, and a diet based on Iranian traditional medicine for the treatment of patients with non-alcoholic fatty liver (NAFLD). RCT Study population: 100 patients have been randomized (Simple block randomization) were selected and divided into four groups. The first group (NAFLD with body mass index (BMI) Less than or equal 27) will be treated with conventional medicine diet, this treatment consists of feeding a diet low in calories and fat. Group II (NAFLD with BMI greater than 27 and less than or equal 30) will be treated with Venostat capsules (500 milligram 2 times a day) and also conventional medicine diet. The third group (NAFLD with BMI less than or equal 27) treated with diet based on Iranian traditional medicine. Group IV (NAFLD with BMI greater than 27 and less than or equal 30) will be treated with diet based on Iranian traditional medicine and also Hepatomelis (herbal tea consisting of *Meslisa officinalis* and *Nigella sativa*) twice daily. Groups I and II (conventional medicine) are considered as the control group, third and fourth groups (Iranian traditional medicine) are considered as intervention group. Patients will be controlled once every two weeks by the physician responsible design. Intervention time 3 months. Primary outcome or consequences of the study: laboratory changes ALT, AST, and Ultrasound Image of liver and changes in body mass index (BMI)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081518807N1**

Registration date: **2015-01-12, 1393/10/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-12, 1393/10/22

Registrant information

Name

Gholam reza Ghayour razmgah

Name of organization / entity

Faculty of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2189

Email address

ghayourgh1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-10-06, 1393/07/14

Expected recruitment end date

2015-04-22, 1394/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Iranian traditional medicine-based diet on Non-alcoholic fatty liver (NAFLD)

Public title

Effect of Iranian traditional medicine-based diet on Non-alcoholic fatty liver (NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 60 years; the detection of Non-alcoholic fatty liver (NAFLD) by Ultrasound Images (grade 1 or 2 or 3). Exclusion criteria: diabetes; heart disease; hypertension; over weight (BMI greater than 30). familial hyperlipidemia; active alcohol or addiction; discourage patients from continuing to participate in the plan; Breastfeeding; Pregnancy; Any other chronic diseases such as kidney stones, gallstones, cardiovascular surgery; abdominal surgery; CVA; acute hepatitis; acute Pancreatitis; major Surgery during the last 6 months and also any surgery on the liver and gallbladder. Rapid weight loss during the last 3 months for any reason. Drop Out Criteria: Any medication side effects during treatment; Other acute illnesses during the study period who had liver adverse impact on yield: Such as gallstones and surgery and general anesthesia and drugs with liver toxicity; Increase in liver enzymes (AST, ALT) and Fasting blood sugar (FBS) during the study period; Consent to continue participating in the study; Alcohol and alcoholic beverages during the study period; Drug use is incorrect; Failure to follow the prescribed diet; Not see the patient during follow up; pregnancy and breastfeeding women participating in the project.

Age

From **20 years** old to **60 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Danegah Street, Vice chancellor for research, University of Medical Sciences, Mashhad

City

Mashhad

Postal code

Approval date

2014-09-09, 1393/06/18

Ethics committee reference number

research.922501.1.1109

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Measure levels of liver enzymes (AST, ALT)

Timepoint

Before the intervention; 6 weeks after the intervention; End of the intervention (3 months)

Method of measurement

Autoanalyzer

Secondary outcomes

1

Description

Ultrasound Images of liver; Fatty tissue infiltration in liver (grade 1 or 2 or 3)

Timepoint

Before the intervention; 6 weeks after the intervention; End of the intervention (3 months)

Method of measurement

The grading of fatty liver infiltration of fat tissue based on ultrasound by one radiologist

2

Description

Body mass index (BMI)

Timepoint

Before the intervention; 6 weeks after the intervention; End of the intervention (3 months)

Method of measurement

Weight and height measurements by one person in the same center.

Intervention groups

1

Description

Control group: the detection of Non-alcoholic fatty liver (NAFLD) by Ultrasound Images (grade 1 or 2 or 3) with body mass index (BMI) Less than or equal 27 will be treated with conventional medicine diet, (this treatment consists of feeding a diet low in calories and fat), and (NAFLD) with BMI greater than 27 and less than or equal 30 will be treated with Venostat capsules (500 milligram 2 times a day) and also conventional medicine diet for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group: NAFLD Patients has Body Mass Index (BMI less than 27) treated with diet based on Iranian traditional medicine and NAFLD patient has body mass index (BMI) greater than 27 and less than or equal 30 will be treated with diet based on Iranian traditional medicine and also Hepatomelis (herbal tea consisting of Melissa officinalis and Nigella sativa) twice daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Gastrointestinal Clinic

Full name of responsible person

Seyyd Musa Al-Reza Hosseini

Street address

Ahmadabad Street ,Ghaem Hospital,Ghaem Gastrointestinal Clinic,Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Faculty of Traditional Medicine Clinic

Full name of responsible person

Gholam reza Ghayour razmgah

Street address

Bahar st - Jahad st - front of Mehran stadium

City

Mashhad

3

Recruitment center

Name of recruitment center

Nutrition clinic of Ghaem Hospital

Full name of responsible person

Mohsen Nematy

Street address

Qaem.Medical.Cente

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Said Islame

Street address

Ghoreish Building, Daneshgah Street, University of Medical Sciences, Vice chancellor for research, Mashhad

City

Mashhad

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 of Mashhad 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

Full name of responsible person

Gholam reza Ghayour razmgah

Position

Phd student Traditional Medicine

Other areas of specialty/work

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Seyyd Musa Al-Reza Hosseini

Position

Subspecialist of Gastroenterology

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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