# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

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

## Protocol summary


**Summary**

Purpose: This study 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 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, Danehgah 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**

Quaem.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**

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**Full name of responsible person**

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**Position**

Phd student Traditional Medicine

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

**Contact**

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Subspecialist of Gastroenterology

**Other areas of specialty/work**

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**Web page address**

## Person responsible for updating data

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**Position**
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**Other areas of specialty/work**

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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*