

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Investigation of the Effect of Dietary Management Based on Iranian Traditional Medicine on Insulin Resistance in patients with Non- Alcoholic Fatty Liver Disease: A controlled clinical trial

Protocol summary

Summary

This study is a controlled clinical trial and investigates the effect of dietary management based on Iranian Traditional Medicine on insulin resistance in patients with non- alcoholic fatty liver disease compared with control group which receive modern diet. First, patients with NAFLD, according to the inclusion criteria approved by gastroenterologist are recruited. Then the patients are informed about the project and presence of case and control groups and after obtaining the consent; they can be enrolled into the project. 88 Patients will be divided in 2 groups randomly. The intervention and control groups fill the forms and questionnaire. The intervention group receive Iranian Traditional Medicine dietary management and control group receive modern dietary recommendation. All patients will fill the food dairy questionnaire. The patients will be visited at months 0, 1, 2 and 3. In each visit the food dairy questionnaire, weight and waist circumferences will be checked. Each patient must perform 70% or more of commands. At the end of study, BMI, waist circumference, lab tests and liver sonography will be done and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040927296N1**
Registration date: **2016-05-03, 1395/02/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-03, 1395/02/14

Registrant information

Name

Zahra Gorji

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

z.gorji@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-30, 1395/02/11

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effect of Dietary Management Based on Iranian Traditional Medicine on Insulin Resistance in patients with Non- Alcoholic Fatty Liver Disease: A controlled clinical trial

Public title

The Effect of Dietary Management Based on Iranian Traditional Medicine on patients with Non- Alcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion: patient between 18 and 60years old; non alcoholic fatty liver (based on positive sonography and rule out of alcohol use; viral hepatitis; hemochromatosis; Wilson disease and autoimmune disease); no cirrhosis; patient with insulin resistance. Exclusion criteria: the reluctance of patients to continue to cooperate; insulin injection; food allergies; liver obstructive diseases and patient hospitalization.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St., Shahid Chamran Highway university of Medical Sciences.

City

Tehran

Postal code

Approval date

2016-03-06, 1394/12/16

Ethics committee reference number

IR.SBMU.REC.1394.161

Health conditions studied

1

Description of health condition studied

Fatty liver disease

ICD-10 code

k70-k77

ICD-10 code description

Diseases of liver

Primary outcomes

1

Description

Insulin resistance

Timepoint

Before intervention and 3 months after intervention

Method of measurement

HOMA-IR formula

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before intervention and months1,2 and after intervention

Method of measurement

Scale and Meter

2

Description

waist circumference

Timepoint

Before intervention and months1,2 and after intervention

Method of measurement

meter

3

Description

Alanine Aminotransferase

Timepoint

Before intervention and at the end of intervention

Method of measurement

Spectrophotometer

4

Description

Aaspartat Aminotransferase

Timepoint

Before intervention and at the end of intervention

Method of measurement

Spectrophotometer

5

Description

Fasting blood sugar

Timepoint

Before intervention and at the end of intervention

Method of measurement

Spectrophotometer

6

Description

quality of life

Timepoint

At the beginning of intervention and at the end of intervention

Method of measurement

Questionnaire (SF-36)

7

Description

HgbA1C

Timepoint

Before intervention and at the end of intervention

Method of measurement

TINIA

8

Description

Serum Insulin

Timepoint

At the beginning of intervention and at the end of intervention

Method of measurement

ECL

9

Description

Serum Albumin

Timepoint

At the beginning of intervention and at the end of intervention

Method of measurement

Spectrophotometer

10

Description

Ferritin

Timepoint

At the beginning of intervention and at the end of intervention

Method of measurement

ELISA

Intervention groups

1

Description

The case group will receive the dietary recommendations based on Iranian traditional medicine designed for fatty liver. This includes elimination of food items that are harmful to liver and addition of items that are beneficial for liver. Each patient will complete the food diary questionnaire everyday which will be evaluated every month. Those patients that have followed less than 70%

of the recommendations will be excluded from study.

Category

Lifestyle

2

Description

The control group will receive modern nutrition dietary recommendations. Each patient will complete the food diary questionnaire everyday which will be evaluated every month. Those patients that have followed less than 70% of the recommendations will be excluded from the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Diseases Clinic in Baqiyatallah Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahmood Mosadegh

Street address

No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran Tehran Tehran Iran, Islamic Republic Of

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Traditional Medicine, Shahid Beheshti 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

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Zahra Gorji

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Full name of responsible person

Zahra Gorji

Position

Ph.D student of Traditional Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Rasool Choopani

Position

Traditional Medicine Specialist, Assistant Professor

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Tehran

Postal code**Phone**

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