Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 atty liver disease compared with control group which receive modern diet. First, patients with NAFLD, according to the inclusion criteria approved by gastroentrologist 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 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
Gasterointestinal 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
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City
Tehran

Postal code

Phone
+98 21 8877 3521

Fax

Email
z.gorji@sbmu.ac.ir z.gorji@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Rasool Choopani

Position
Traditional Medicine Specialist, Assistant Professor

Other areas of specialty/work

Street address
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City
Tehran

Postal code

Phone
+98 21 8877 3521

Fax

Email
rchoopani@sbmu.ac.ir

Web page address

Person responsible for updating data

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
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City
Tehran

Postal code

Phone
+98 21 8877 3521

Fax

Email
z.gorji@sbmu.ac.ir

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