Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effects of Acupuncture with Weight Loss Diet on Metabolic Parameters in Patients with Non-Alcoholic Fatty Acid Liver: Randomized Controlled Single-Blinded Clinical Trial

Protocol summary

Study aim

The effects of acupuncture with a weight loss diet on metabolic status in patients with NAFLD

Design

The clinical trial is a phase 3, single-blind, controlled (sham) study with 60 patients. Randomization will be conducted using RAS software.

Settings and conduct

The study will be conducted on 60 eligible volunteers for 8 weeks. Sampling will be done through announcements at the Ahmadieh Centeor through referrals from gastroenterology specialists. Patients will be randomly assigned (using RAS software) and will be followed for eight weeks. The individuals in both groups will be matched for age, gender, and NAFLD grade. Additionally, all participants will be monitored by a nutrition specialist. Diet will consist of 50% carbohydrates, 20% protein, and 30% fat, with a calorie deficit of 500 kcal from the total energy needs calculated for each individual. Blinding for patients will be achieved through sham treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both sexes NAFLD with grades 2 or 3 Age range: 20-65 years Exclusion Criteria: Individuals with chronic thyroid disorders, autoimmune disorders, various malignancies, and liver diseases other than non-alcoholic fatty liver disease, including types of hepatitis (A, B, C), Wilson's disease, Crohn's disease, uncontrolled diabetes, and hemochromatosis Pregnant or breastfeeding women

Intervention groups

1.Intervention Group: Acupuncture with a weight loss diet. 2.Control (Sham) Group: Sham acupuncture with a weight loss diet.

Main outcome variables

Liver Fatty Grade, Liver Enzymes (Aspartate Aminotransferase, Alanine Aminotransferase), Weight and Body Mass Index, Fasting Blood Sugar, Total Cholesterol, Triglycerides , LDL Cholesterol, HDL Cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110314006065N5**
Registration date: **2025-03-01, 1403/12/11**
Registration timing: **prospective**

Last update: **2025-03-01, 1403/12/11**
Update count: **0**

Registration date

2025-03-01, 1403/12/11

Registrant information

Name
Nazli Namazi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of Acupuncture with Weight Loss Diet on Metabolic Parameters in Patients with Non-Alcoholic Fatty Acid Liver: Randomized Controlled Single-Blinded Clinical Trial

Public title
Acupuncture and Fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-alcoholic fatty liver disease (NAFLD) with grades 2 or 3
Exclusion criteria:
Individuals with chronic thyroid disorders Autoimmune disorders Various malignancies Liver diseases other than non-alcoholic fatty liver disease, including types of hepatitis (A, B, C) Wilson's disease Crohn's disease Uncontrolled diabetes Hemochromatosis Alcohol consumers and hepatotoxic substances Adherence to traditional treatment methods including the use of herbal medicine for treating NAFLD Pregnant or breastfeeding women
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to allocate participants to the two study arms (intervention and control groups), simple randomization will be used. This method is designed to ensure a fair and unbiased distribution of participants between the groups and to reduce the impact of confounding factors. After screening and confirming eligibility for the study, a list of qualified participants will be created. Then, using the RAS software, a random sequence for allocating participants to the study groups will be generated. In this method, information regarding the number of groups and sample size is input into the software, which then generates random numbers accordingly. The output is a list equal to the sample size, divided into the two groups. Therefore, the allocation of individuals to one of the two groups will be completely random and unpredictable. Based on this list, it will be determined whether an individual entering the study is placed in the acupuncture group or the control group. The allocation of individuals to one of the two study groups is concealed, and participants are unaware of their assigned group. After generating the random chain in the software, qualified individuals are assigned a code from 1 to 60 based on their entry time into the study. Based on the pre-established sequence and the individual's code, it will be determined which group they are allocated to
Blinding (investigator's opinion)
Single blinded
Blinding description
Acupuncture is performed at sites other than the treatment points for fatty liver in the sample group
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Endocrinology and Metabolism research Institude-Tehran University of Medical Sciences
Street address
Jalal-e-Al-Ahmad Highway-Next to Shariati Hospital, Tehran
City
Tehran
Province
Tehran
Postal code
1411713119
Approval date
2025-01-19, 1403/10/30
Ethics committee reference number
IR.TUMS.EMRI.REC.1403.118

Health conditions studied

1

Description of health condition studied
Non-Alcoholic Fatty Liver Disease (NAFLD)
ICD-10 code
K76
ICD-10 code description
Other diseases of liver

Primary outcomes

1

Description
Liver enzymes
Timepoint

Baseline and the end (8th weeks)

Method of measurement

Enzymetic

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Baseline and End (8th week)

Method of measurement

Enzymatic

2

Description

Total cholesterol (TC)

Timepoint

Baseline and End (8th week)

Method of measurement

Enzymatic

3

Description

Triglyceride (TG)

Timepoint

Baseline and End (8th week)

Method of measurement

Enzymatic

4

Description

Low lipoprotein density cholesterol (LDL-C)

Timepoint

Baseline and End (8th week)

Method of measurement

Enzymatic

5

Description

High-density lipoprotein cholesterol (HDL-C)

Timepoint

Baseline and End (8th week)

Method of measurement

Enzymatic

6

Description

Weight

Timepoint

Baseline and End (8th week)

Method of measurement

Scale

7

Description

Body mass index (BMI)

Timepoint

Baseline and End (8th week)

Method of measurement

Dividing weight to square of height in meter

Intervention groups

1

Description

Intervention group: The participants will receive acupuncture (twice a week) along with a weight loss diet. The individuals involved in this treatment will be monitored by a nutrition specialist. The diets will consist of 50% carbohydrates, 20% protein, and 30% fat, and will have 500 kilocalories subtracted from the total energy requirement calculated for each individual to facilitate weight loss. Additionally, to receive acupuncture, participants will visit the Ahmadieh Health Center, affiliated with Tehran University of Medical Sciences, twice a week. Each session will last 45 minutes and will consider acupuncture points specified for NAFLD (Non-Alcoholic Fatty Liver Disease) in recognized acupuncture resources, conducted by a Chinese medicine specialist. The acupuncture points of interest are as follows: Ren 12, Ren 14, Ren 10, Stomach 36, Liver 3, Liver 2, Stomach 40, Stomach 36, Spleen 9, Stomach 44, Liver 13.

Category

Treatment - Other

2

Description

Control group: A group receiving acupuncture (at points other than those for treating fatty liver) along with a weight-loss diet. Participants in this treatment will be supervised by a nutritionist. The diets will consist of 50% carbohydrates, 20% protein, and 30% fat, with a reduction of 500 kilocalories from the total energy requirement calculated for each individual for weight loss. Additionally, sham acupuncture will be used for the purpose of masking the patient. Sham acupuncture will be performed at points other than those for treating non-alcoholic fatty liver, using the same number of needles (11 points). Participants will visit the Ahmadieh Health Center affiliated with Tehran University of Medical Sciences twice a week. Each session will last 45 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadiyeh Center-Tehran University of Medical Sciences

Full name of responsible person

Hooman Kazemi Motlaq

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available