Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of herbal syrup based on Persian medicine containing turmeric (Curcuma longa), lemon (citrus lemon), pomegranate (Punica granatum) and sumac (Rhus coriaria L) on metabolic status in patients with non-alcoholic fatty liver(NAFLD): A randomized clinical trial

Protocol summary

Study aim
Determining the effects of herbal syrup on metabolic status in patients with non-alcoholic fatty liver disease

Design
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial of 50 patients. Computer-assisted randomization (RAS) will be used for randomization. The sequence will be performed in permutation blocks of four, with patients stratified according to gender and fatty liver status.

Settings and conduct
Ahmadiyeh Health Center The principles of blinding are that both the drug and placebo are indistinguishable in terms of color, size, odor, shape, weight, and packaging. This blinding will be maintained throughout the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Both male and female• 2- Patients with NAFLD grade 2 or 3 3- Age range 20 to 65 years Exclusion criteria: 1- People with chronic thyroid disorders, autoimmune disorders, various malignancies, various liver diseases except non-alcoholic fatty liver including hepatitis (A, B, C), Wilson's disease, Crohn's disease, uncontrolled diabetes, hemochromatosis 2- Alcohol users and hepatotoxic patients 3- Following other complementary therapies to treat NAFLD 4- Pregnant or breastfeeding women

Intervention groups
The intervention group, in addition to dietary instructions, uses herbal syrup to improve its effect on the liver and change the grade of fatty liver. The control group receives placebo and dietary instructions related to the disease. Participants will be followed up by the researcher for eight weeks.

Main outcome variables
Fatty liver grade; Liver changes in Fibroscan; Liver enzymes (Ast-Alt)

General information

Reason for update

Acronym
TFLS

IRCT registration information
IRCT registration number: **IRCT20250911067210N1**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **prospective**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date
2025-09-26, 1404/07/04

Registrant information

Name
Azadeh Zarei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8897 6527

Email address
azarei@sina.tums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of herbal syrup based on Persian medicine containing turmeric (Curcuma longa), lemon (citrus lemon), pomegranate (Punica granatum) and sumac (Rhus coriaria L) on metabolic status in patients with non-alcoholic fatty liver(NAFLD): A randomized clinical trial

Public title
Studying the effect of herbal syrup on fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Both male and female Patients with grade 2 or 3 NAFLD Age range 20 to 65 years

Exclusion criteria:
People with chronic thyroid disorders Autoimmune disorders Types of malignancies Various liver diseases, except non-alcoholic fatty liver disease, including hepatitis (A, B, C) Wilson's disease Crohn's disease Uncontrolled diabetes Hemochromatosis Alcohol users and hepatotoxicants Following other complementary therapies to treat NAFLD Pregnant or breastfeeding women

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using computer-assisted randomization (RAS). The sequence will be in permutation blocks of four, with patients stratified according to gender and fatty liver status. Except for the study pharmacist who will provide the randomization list and sequential numbering of the drug, the other investigators and all patients will not be aware of this list. The sequence of allocation is sealed and concealed by sequential numbering.

Blinding (investigator's opinion)
Double blinded

Blinding description
The principles of blinding are that neither the drug nor the placebo are distinguishable in color, size, odor, shape, weight, or packaging. This blinding will be maintained throughout the study, and only the pharmacist will be aware of the allocation. Randomized, coded allocation boxes were used to conceal the drug and placebo and prevent their identification. The pharmacist will ensure that neither the participants nor the researchers will be aware of the contents of the boxes until the end of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Keshavarz Boulevard - Intersection of Qods Street - Central Building of Tehran University of Medical Sciences - 6th Floor - Room 604

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2025-07-29, 1404/05/07

Ethics committee reference number
IR.TUMS.TIPS.REC.1404.045

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver grade change in Fibroscan examination

Timepoint
At the beginning of the study and after eight weeks at the end of the treatment intervention

Method of measurement
Fibroscan device

Secondary outcomes

1

Description
Changes in liver enzymes
Timepoint
At the beginning of the study and after eight weeks of therapeutic intervention at the end of the study
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: The intervention is based on the prescription of a herbal syrup formulation prepared from turmeric, sumac, pomegranate, and lemon. Turmeric and sumac are purchased from the pharmaceutical market and approved by the herbarium and receive a herbarium code. Pomegranate is purchased in the form of pomegranate paste from a specific brand, as well as lemon juice from a specific brand. 20 grams of turmeric root powder and 10 grams of sumac powder are boiled in 500 ml of water for 20-30 minutes, then strained and 20 grams of pomegranate paste and 20 grams of lemon juice are added to it. Stevia, xantham gum, and edible glycerin are used for flavoring and consistency.
Category
Treatment - Drugs

2

Description
Control group: The placebo formulation is made using non-medicinal ingredients such as stevia, xantham gum, edible glycerin, permitted food coloring, and pomegranate essential oil, and a small percentage of lemon juice (5% of the drug).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadiyeh Health Center
Full name of responsible person
Azadeh Zarei
Street address
North Sarparast Street, Beginning of West Taleghani Street, Palestine Square
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8897 6527
Email
drzarei.azadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Keshavarz Boulevard - Intersection of Qods Street - Central Building of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 81631
Email
tumspr@tums.ac.ir
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
Tehran University of Medical Sciences
Full name of responsible person
Azadeh Zarei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Palestine Square, beginning of West Taleghani Street,

North Sarparast Street, Faculty of Persian Medicine
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8897 6527
Email
drzarei.azadeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehrdad Karimi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Palestine Square, beginning of West Taleghani Street, North Sarparast Street, Faculty of Persian Medicine
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8897 6527
Email
Mehrdadkarimi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azadeh Zarei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Palestine Square, beginning of West Taleghani Street, North Sarparast Street, Faculty of Persian Medicine
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8897 6527
Email
drzarei.azadeh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identification.
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Researchers working in academic and scientific institutions and people who are also involved in industry
Under which criteria data/document could be used
To improve the process of drug research and production
From where data/document is obtainable
Vice President for Research, Faculty of Iranian Medicine, Tehran University of Medical Sciences
What processes are involved for a request to access data/document
The request is accepted via email and upon approval by the project implementation team.
Comments