

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Rheum Palmatum syrup (traditional medicine product) with diet and exercise in comparison with diet and exercise alone on liver enzymes in patients with non-alcoholic fatty liver (NAFLD)

Protocol summary

Study aim

Determining the effect of Rheum Palmatum syrup (traditional medicine product) with diet and exercise in comparison with diet and exercise alone on liver enzymes in patients with non-alcoholic fatty liver

Design

Two arm parallel groups randomized controlled trial on 50 patients, random allocation software was used for randomization.

Settings and conduct

Fifty patients referred to the Liver and Gastroenterology Clinic of Imam Khomeini Hospital who suffer from non-alcoholic fatty liver are randomly assigned to one of the two intervention or control groups. At the end of the treatment period, the drug will be discontinued and liver tests will be repeated and recorded. The patients will be followed up for another three months without receiving medication, and at the end of three months, liver and sono tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 60 years and also fatty liver disease based on high liver enzymes with the diagnosis of a gastroenterologist and exclusion criteria includes: type 1 and type 2 diabetes require medication, positive serology for viral hepatitis B and C, Liver and kidney disease, Blood pressure-requiring medication (BP>130/85 mmhg), Liver cirrhosis, Pregnancy and lactation, Hyperlipidemia requiring medication TG> 150 mg / dl, Taking drugs such as valproate, amiodarone, methotrexate, tamoxifen, corticosteroids, hypothyroidism require medication and active malignancy in the body.

Intervention groups

Intervention group: Receiving Rheum Palmatum syrup along with receiving diet modification training and exercise Control group: receive diet modification and exercise training

Main outcome variables

ALT level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211019052813N1**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Mina Mohebbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3358 7989

Email address

dr.m_mohebi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Rheum Palmatum syrup (traditional medicine product) with diet and exercise in comparison with diet and exercise alone on liver enzymes in patients with non-alcoholic fatty liver (NAFLD)

Public title
Rheum Palmatum syrup and NAFLD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 60 years Fatty liver disease based on high liver enzymes
Exclusion criteria:
Type 1 and type 2 diabetes (requires medication)
Positive serology of viral hepatitis B and C (anti-HCV or HBsAg positive) Liver and kidney disease Blood pressure-requiring medication (BP> 85/85 mmhg) Liver cirrhosis
Pregnancy and lactation Hyperlipidemia (requires medication TG> 150mg / dl) Wilson and hemochromatosis Autoimmune hepatitis Taking drugs such as valproate, amiodarone, methotrexate, tamoxifen, corticosteroids Hypothyroidism (requires medication) Active malignancy in the body

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected according to the inclusion criteria and then randomly assigned to the experimental and control groups according to the random sequence obtained through random allocation software.

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

Approval date

2021-10-13, 1400/07/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.749

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

K76.0Fatty (change of) liver, not elsewhere classified
Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description

Liver enzymes (ALT, AST)

Timepoint

Baseline, after one month and after three months from the beginning of the study

Method of measurement

Measurement of serum levels of serum enzymes quantitatively

2

Description

Body mass index

Timepoint

Baseline, after one month and after three months from the beginning of the study

Method of measurement

weight in kilograms divided by height in meters squared

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving Rheum Palmatum syrup along with receiving exercise instructions and diet modification training

Category

Treatment - Drugs

2

Description

Control group: Receiving exercise instructions and diet modification training

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Liver Clinic of Imam Khomeini Hospital

Full name of responsible person

Ebrahim Khadem Azghadi

Street address

Sarparast Ave; Taleghani St, Faculty of Persian medicine; Tehran University of Medical Sciences, Tehran, Iran.

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1417653761

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+98 21 6675 4167

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ekhadem@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Sixth floor, Keshavrz Blvd., Ghods Ave., Tehran University of Medical Sciences

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vcr@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

Mina Mohebbi

Position

Assistant of Iranian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Number 110 yoosef yadi street, shaghayegh avenue, daneshjoo Blvd

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Postal code

1417653761

Phone

+98 17 3358 7989

Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

After the study, information about the main outcome will
be shared

**When the data will become available and for how
long**

6 months after the publication of the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Data and results will be available to all researchers for
NAFLD research.

From where data/document is obtainable

Email to dr.m_mohebi@yahoo.com

**What processes are involved for a request to access
data/document**

The data will be provided to the applicant within one
month after reviewing and confirming the request.

Comments