

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

To Evaluate the Efficacy of Rivandi Syrup on Non-Alcoholic Fatty Liver Patients

Protocol summary

Study aim

Determining the effect of Rivandi syrup in patients with non-alcoholic fatty liver referred to the clinics of the Medical University of Tehran in 2023 1- Determining and comparing the level of Aspartate transferase (AST) before and after 2- Comparing the level of alanine aminotransferase (ALT) 3 - Comparing the level of controlled attenuation parameter (CAP) fibroscan 4 - Determining and comparing the level of fibrosis liver stiffness measurement(LSM) index 5- Comparing body mass index

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase two on 50 patients. A number of 50 patients were selected based on the inclusion criteria and after performing a fibroscan and fatty liver confirmation. After randomly coding all 4 patients (blocks of 4) according to the time of entering the RCT (randomization with RANDBetween function of Excel software) from A to D. Examined by a specialist and receive the drug or placebo according to its label and are examined. One group is prescribed Rivandi syrup (25 people) and the second group (25 people) is prescribed placebo.

Settings and conduct

Patients with non-alcoholic fatty liver disease who refer to the affiliated clinics of Tehran University of Medical Sciences will be evaluated

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 20-60 years with non-alcoholic fatty liver according to the approval of the fibroscan device Exclusion criteria: Diagnosis of acute diseases that have a bad effect on liver function, such as gallstones and surgery History of alcohol consumption and alcoholic beverages Pregnancy or breastfeeding Patients with hypokalemia

Intervention groups

Case Patients: Prescribe Rivandi Syrup for 3 months
Control Patients: Prescribe placebo syrupe for 3 months

Main outcome variables

Controlled Attenuation Parameter (CAP) Liver Stiffness Measurement(LSM)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220529055009N1**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **retrospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Mohammad Shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 4078

Email address

mohamad.shahbazi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
To Evaluate the Efficacy of Rivandi Syrup on Non-Alcoholic Fatty Liver Patients

Public title
The Effect of Rivandi Syrup on Non-Alcoholic Fatty Liver

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Non Alcoholic Fatty Liver Patients
Exclusion criteria:
Diabetes, Hypertension, Familial Hyper Lipedema, Chronic Heart Disease Alcohol Use Pregnancy, Lactation

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, a block of 4 (A-B-C-D) is created, and bottles of drugs or placebos have one of these four labels. In it, there are two letters of drug and two letters of placebo (for example, A and D for drug and B and C for placebo). According to the order of the patients' referral to the plan and after obtaining written consent, the patient will be placed in one of the 4 groups randomly (lottery), and after 4 patients enter the RCT and the end of the 4-pack, another 4-pack will be opened for the 5th to 8th patients. can be Medicines labeled A to D are delivered to Salamat Kedeh pharmacy and the patient receives the medicine with that label after drawing a lottery and getting the letter A, B, C, or D.

Blinding (investigator's opinion)
Double blinded

Blinding description
Bottles of drugs with labels A to D are made by the pharmacist and delivered to the Salamat Kode pharmacy, which two labels are drug and two are placebos, and the pharmacist only knows the contents of each bottle. Patients receives that label and until the end of the RCT (3 Months), it is delivered to him with all the initial labels

Placebo
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 (TUMS)

Street address

6th Floor- Central building of TUMS- Qods St- Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-05-23, 1401/03/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.167

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

CAP (Controlled Attenuation Parameter) Index in Fibroscan

Timepoint

0 and 3 Months

Method of measurement

Fibroscan Device

2

Description

LSM (Liver Stiffness Measurement) in Fibroscan

Timepoint

0 and 3 Months

Method of measurement

Fibroscan Device

Secondary outcomes

1

Description

Blood Serum Aspartate Transferase (AST)

Timepoint

0 and 3th months

Method of measurement

Blood Test

2

Description

Blood Test Alanine aminotransferase (ALT)

Timepoint

0 and 3th months

Method of measurement

Laboratory Blood Test

3

Description

Blood Test Alkaline phosphatase (ALP)

Timepoint

0 and 3th months

Method of measurement

Laboratory Blood Test

4

Description

Body Mass Index (BMI)= ratio of person's weight in kilograms and height in metres squared

Timepoint

0 and 3th months

Method of measurement

Standard Scale

Intervention groups

1

Description

Intervention group: rhubarb syrup is prepared in the pharmacy laboratory of the Faculty of Traditional Medicine of Tehran University of Medical Sciences (Jalinian medicine) with the combination of Chinese rhubarb, Fumitory and Dodder, whose herbarium code is obtained from the Faculty of Pharmacy of the university, and in 250 bottles CC is provided to patients. Consuming it as one tablespoon three times a day (breakfast, before lunch and before bed)

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup is prepared in the pharmaceutical laboratory of the Faculty of Traditional Medicine of Tehran University of Medical Sciences and is available to patients in 250 cc bottles. Consuming it as

one tablespoon three times a day (before breakfast, before lunch and before bed)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of medical science (Ahmadiieh Clinic)

Full name of responsible person

Hamid Ghaderi

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North Sarparast St- Felestin Sq

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Web page address

<https://spm.tums.ac.ir/contact-us.html>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Street address

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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

20

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

Postal code

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Full name of responsible person

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Other areas of specialty/work

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City

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Province

Tehran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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