Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 21 2208 4078
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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 (Ahmadieh Clinic)
Full name of responsible person
Hamid Ghaderi
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North Sarparast St- Felestin Sq
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Phone
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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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spm@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
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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Rezaeizadeh
Position
Associate Professor
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Person responsible for updating data

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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