Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Evaluation of the effect of Ciochorium intibus syrup on clinical and para clinical manifestations of patients with non-alcoholic fatty liver

Protocol summary

Study aim

Evaluation of the effect of Ciochorium intibus syrup on clinical and para clinical manifestations of patients with non-alcoholic fatty liver

Design

This clinical trial is conducted on 100 patients in two groups of 50, including a control group and parallel groups. This study is single-blind and simple randomization is used

Settings and conduct

This study is carried out on patients with active fatty liver of grade 2 and higher (high liver enzymes and ultrasound evidence) referring to Qaem and Imam Reza hospitals in Mashhad.These patients have no involvement in active chronic hepatitis, active viral hepatitis, metabolic liver diseases, autoimmune diseases, drug side effects and do not consume alcohol, and are randomly assigned to two groups receiving drug treatment for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria : age of over 20 and below 60; higher than 40 alanine aminotransferase and aspartate aminotransferase serum levels; fatty liver with grade 2 and higher; body mass index of over 27 Exclusion criteria : pregnancy and breastfeeding; use of alcohol; previous history of confirmed liver diseases; use of any diet or drug for the treatment of fatty liver within the last 3 months; autoimmune diseases and all types of malignancy

Intervention groups

Intervention group: Patients are treated with Ciochorium intibus syrup for two months, receiving 8 cc of the syrup three times a day, half an hour before each meal. Metformin is also given as the common drug. Control group: The control group receives placebo syrup. Metformin is also given as the common drug.

Main outcome variables

Changes in fatty liver grade; serum levels of alanine aminotransferase and aspartate aminotransferase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181023041431N1**
Registration date: **2019-03-09, 1397/12/18**
Registration timing: **prospective**

Last update: **2019-03-09, 1397/12/18**
Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Hossein Ramezani hodk

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3225 4307

Email address

ramezanihh2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Ciochorium intibus syrup on clinical and para clinical manifestations of patients with non-alcoholic fatty liver

Public title
Effectiveness of Ciochorium intibus syrup on non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of over 20 and below 60 Higher than 40 alanine aminotransferase and aspartate aminotransferase serum levels Fatty liver with grade 2 and higher Body mass index of over 27
Exclusion criteria:
Pregnancy and breastfeeding Use of alcohol Previous history of confirmed liver diseases Use of any diet or drug for the treatment of fatty liver within the last 3 months Confirmed autoimmune diseases All types of malignancy
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be based on a random allocation table provided by a computer. In order to conceal the random allocation of the groups, sealed envelopes will be used. Then, the envelopes are opened in sequence for each patient and the method of treatment becomes known.
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind study in which the participants are unaware of their treatments, and the type of drug treatment is based on sealed envelopes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-04-11, 1397/01/22
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.704

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
Serum level of alanine aminotransferase
Timepoint
At the beginning of the study (before the intervention) and at the end of the intervention
Method of measurement
Biochemical tests

2

Description
Serum level of aspartate aminotransferase
Timepoint
At the beginning of the study (before the intervention) and at the end of the intervention
Method of measurement
Biochemical tests

3

Description
Change in fatty liver grade
Timepoint
Before and after intervention
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are treated with Ciochorium intibus syrup for two months, receiving 8 cc of the syrup three times a day, half an hour before each meal. Metformin is also given as the common drug.
Category
Treatment - Drugs

2

Description
Control group: The control group receives placebo syrup. Metformin is also given as the common drug.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Dr Seyed Mousareza Hoseinin
Street address
Ghaem hospital, Ahmad Abad Ave
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9176699199
Phone
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HoseiniMR@mums.ac.ir

2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hossein Ramezani
Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Seyed Mousareza Hoseini
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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ramezanihh@mums.ac.ir

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
Yes - There is a plan to make this available
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 can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.
Under which criteria data/document could be used
Carrying out analysis on data is permitted.
From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.
What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.
Comments