

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 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 Clochorium 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

City

Mashhad

Province

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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

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

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 scientific inquiries

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Person responsible for updating data

Contact

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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