

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the therapiotic effect of quince oxymel on treatment of non-alcoholic fatty liver disease - Randomized clinical Trial, triple Blinded, placebo controlled

Protocol summary

Study aim

Determining the effect of quine oxymel consumption on the indicators of non-alcoholic fatty liver

Design

Clinical trial with a control group, with parallel groups, three blinded, randomized, phase 2 on 80 patients.
Randomization by block randomization method

Settings and conduct

The project will be performed in Gastroenterology Specialist Clinic, Doctors City, Qom City of Qom University. After obtaining written informed consent, people who meet the criteria for entering the study will receive the drug or placebo with the same packaging and similar in terms of appearance, color, and scent randomly. A special code label is installed on the syrup by the pharmaceutical consultant. The drug will be provided to the doctor and plan executive and the patient. The code of each syrup, specific to each patient, will be inserted in the patient's file and checklist by the administrator. And at the end of the study, for statistical analysis, the information and checklist form of the patients will be provided to the statistics consultant

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 65 Fatty liver grade two and above Liver enzymes are higher than normal level
Exclusion criteria : Diabetes, viral hepatitis, and autoimmune and metabolic causes History of alcohol consumption

Intervention groups

Eighty fatty liver patients will be randomly divided into intervention and control groups. The intervention group will be treated with ten milliliters of saffron syrup and quine oxymel three times a day, half an hour before meals, and the control group will be treated with placebo syrup in the same way.

Main outcome variables

Grade of non-alcoholic fatty liver in sonography report

General information

Reason for update

Changing the study start and end dates, Modifying the study site

Acronym

IRCT registration information

IRCT registration number: **IRCT20221202056689N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**

Update count: **2**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Mehrdad Ababaf Shoshtari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3333 1786

Email address

mababaf@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

2023-07-06, 1402/04/15

Actual recruitment end date

2024-10-01, 1403/07/10

Trial completion date

2024-10-01, 1403/07/10

Scientific title

Investigating the therapeutic effect of quince oxymel on treatment of non-alcoholic fatty liver disease - Randomized clinical Trial, triple Blinded, placebo controlled

Public title

Investigating the effect of quince oxymel on non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between the ages of 20 and 65 years are diagnosed with grade 2 or higher fatty liver based on the ultrasound report liver enzymes that are higher than the normal level.

Exclusion criteria:

Having diabetes Viral hepatitis and autoimmune hepatitis Having metabolic diseases such as Wilson's disease and hemochromatosis History of alcohol consumption and alcoholic beverages Liver transplant at some point in the past Taking any type of medicine to treat fatty liver in the past one month The patient's unwillingness to continue the plan Severe allergy or drug complication Pregnancy and breastfeeding Taking Varfarin, heparin compounds and anticoagulant drugs

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Actual sample size reached: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients will be by block randomization method. For this purpose, the volume of each block is four people, and the number of blocks required for the study is equal to 20 four-person blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A special code will be considered for each syrup and this code will be recorded on the syrup label. Only the pharmacist consultant will know about the drug codes. Medicines will be provided to the doctor and plan administrator and the patient. The code of each syrup,

specific to each patient, will be inserted in the patient's file and checklist by the administrator. At the end of the study, the information and checklist form of the patients will be provided to the statistics consultant for statistical analysis, and after the data analysis, the code of the syrups will be provided to the administrator and the statistics consultant for the final analysis. syrups in intervention and comparison groups are similar according to color, smell, shape and route of use.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of qom University of Medical Sciences

Street address

No. 83, 4th Alley, Jihad University Street, Safashehr Street, Qom

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Postal code

3716993456

Approval date

2022-11-21, 1401/08/30

Ethics committee reference number

ir.muq.rec.1401.176

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**

Non-alcoholic fatty liver grade

Timepoint

At the beginning of the study (before the start of the intervention) and twelve weeks after the intervention

Method of measurement

ultrasound device

2

Description

Alanine aminotransferase enzyme

Timepoint

در ابتدای مطالعه (قبل از شروع مداخله) و دوازده هفته بعد از مداخله

Method of measurement

Measuring the serum level of alanine aminotransferase enzyme in peripheral blood samples

3

Description

Aspartate aminotransferase

Timepoint

در ابتدای مطالعه (قبل از شروع مداخله) و دوازده هفته بعد از مداخله

Method of measurement

اندازه گیری سطح سرمی آنزیم آسپارتات آمینو ترانسفراز در نمونه خون محیطی

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group Patients with fatty liver referred to the Gastroenterology Specialist Clinic, Doctors City, Qom City are selected according to the entry criteria and randomly divided into intervention and control groups. The patients of the intervention group are treated with ten milliliters of quine oxymel syrup three times a day, half an hour before meals, for twelve weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients with fatty liver referred to the gastroenterology clinic of Gastroenterology Specialist Clinic, Doctors City, Qom City are selected according to the entry criteria and randomly divided into intervention and control groups. Control group patients are treated with ten milliliters of placebo three times a day, half an hour before meals for twelve weeks. The placebo is made in the laboratory of Iranian Medicine Faculty of Qom University

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctors' City Gastroenterology Subspecialty Clinic in Qom City

Full name of responsible person

Mehrdad Ababaf Shushtri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Rahim Aali

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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

Ghous 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

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

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Full name of responsible person

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Position

PhD specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data related to the outcome of the study include the changes in the grade of fatty liver in the sonography report and the changes in liver enzymes that can be shared.

When the data will become available and for how

long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers of academic and scientific institutions

Under which criteria data/document could be used

Use in the treatment of patients and use in scientific articles

From where data/document is obtainable

Dr. Fatemeh Ali Asl, Assistant Professor, Faculty of Traditional Medicine, Qom University. . Mehrdad Ababaf

Shushtri, Ph.D. Specialist Assistant, Faculty of Traditional Medicine, University of Qom. .

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

Send a request by email and receive a response within two working weeks

Comments

This study is the first clinical trial to investigate the effect of lemon jelly in the treatment of non-alcoholic fatty liver disease.