Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of metformin and livergol in liver enzymes in patients with non-alcoholic fatty liver

Protocol summary

Study aim
Comparison of the effect of metformin and livergol on liver enzymes in patients with non-alcoholic fatty liver

Design
The present clinical trial study was designed as a single-blind, randomized, block-based study with a control group and a parallel group of a total of 80 patients.

Settings and conduct
A total of 80 patients with non-alcoholic fatty liver disease referred to Qazvin Hospital will be randomly divided into two treatment groups. Randomization of patients is done by balanced block randomization method with blocks with size of 4. Then the variables of the first phase of the study are determined from both groups, the treatment period will be done for 2 months and to group A metformin 500 mg in such a way that in the first 2 weeks of each meal half a pill and after two weeks gradually increase. Group B is given 140 mg Livegol tablets, after two months the patients' liver enzymes are checked and the results are compared in the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years Non-alcoholic fatty liver based on ultrasound Increase in liver enzymes to normal Exclusion criteria: People with suspected fatty liver disease according to their history in terms of history of alcohol consumption, presence of other concomitant diseases such as hepatitis B, C, insulin use Pregnancy Taking effective LFT drugs

Intervention groups
Group A: Metformin 500 mg in such a way that in the first 2 weeks of each meal, half a pill is increased and after two weeks, it is gradually increased. Group B: Livergol tablets are given 140 mg

Main outcome variables
BMI، Ch، TG، LDL، HDL، BS، SGOT، SGPT، ALP, Degree of liver steatosis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210514051287N1**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date
2022-03-04, 1400/12/13

Registrant information
Name
tahera mahdavi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3377 7176
Email address
dr.amirrezakhazzaei@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-09, 1401/01/20
Expected recruitment end date
2022-08-11, 1401/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the effect of metformin and livergol in liver enzymes in patients with non-alcoholic fatty liver

Public title
Comparison of metformin and livergol in patients with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Non-alcoholic fatty liver based on ultrasound increase liver enzymes above normal
Exclusion criteria:
People with suspected fatty liver disease according to history in terms of alcohol consumption, the presence of other concomitant diseases such as hepatitis B, C, insulin use Pregnancy Taking effective LFT drugs
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients is done by balanced block randomization method with blocks with size of 4. For allocation concealment group names will be placed in envelopes. the envelopes will be numbered from 1 to 80 and will be put in the box, respectively. The researcher who makes the random assignment will be aware of the contents of the envelopes. The content of the envelopes indicates the study groups. After ensuring that sample enters the research and obtains written consent, The first envelope is elected in order of numbers and patient is appointed in one of the study groups according to the contents of the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is a single-blind study in which the two drugs studied in this study in terms of all physical characteristics, including; Shape, color, taste, size and packaging are simulated to enable blinding at the participant level.
Placebo
Not used
Assignment
Parallel
Other design features
Statistical analysis of data will be performed using SPSS statistical software version 20. To describe the data from the mean and standard deviation and absolute and relative frequency and for the analytical part after the normality check of the data using Kolmogorov-Smirnov test from independent two-sample t-test, ANOVA, and in case Relevant parametric bread tests will be used for data abnormality

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Shahid Beheshti St., Clinical Research Development Center
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2021-05-05, 1400/02/15
Ethics committee reference number
IR.QUMS.REC.1400.053

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
TG
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

2

Description
Ch
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

3

Description
LDL
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

4

Description
HDL
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

5

Description
BS
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

6

Description
SGPT
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

7

Description
SGOT
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on turbidometric tests

8

Description
BMI
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Based on measurement and calculation

9

Description
Degree of liver steatosis
Timepoint
Before intervention and 2 months after intervention
Method of measurement
According to the pathology report

Secondary outcomes

1

Description
Patient recovery rate
Timepoint
Two months later the intervention
Method of measurement
Based on examination and tests

2

Description
Side effects of treatment
Timepoint
Two months later the intervention
Method of measurement
Based on examination and tests

Intervention groups

1

Description
First, the studied variables are evaluated before the intervention, then this group will receive metformin (N,N-dimethylbiguanide) with the chemical composition of C4H11N5 and a dose of 500 mg produced by Dr. Abidi Pharmaceutical Company orally. As they will be explained in the first visit, they should take half a tablet (250 mg) in breakfast and lunch for the first 2 weeks, and after two weeks, they will return again to order the use of one metformin tablet (500 mg) to receive .After two months of treatment, they will come again to check for the desired variables.
Category
Treatment - Drugs

2

Description
First, the studied variables are evaluated before the start of the intervention, then this group will receive Livergol drug (dried extract, sage extract) at a dose of 140 mg produced orally by Dr. Abidi Pharmaceutical Company. In the first visit, this group will be instructed to take one tablet (140 mg) daily for two months and to refer again after two months to check the desired variables.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Tahereh Mahdavi
Street address

Qazvin, Minoodar, taavon Square, Independent Educational and Medical Center of the province

City
Qazvin

Province
Qazvin

Postal code
3464186699

Phone
+98 28 3379 0611

Email
dr.amirrezakhazzaei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyyed Mehdi Mirhashemi

Street address
Shahid Beheshti St., Deputy of Research and Technology

City
Qazvin

Province
Qazvin

Postal code
3415613911

Phone
+98 28 3333 6001

Email
sm.mirhashemi@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Tahereh Mahdavi

Position
General medicine student

Latest degree
A Level or less

Other areas of specialty/work
Internal Medicine

Street address
Qazvin, Minoodar, taavon Square, Provincial Educational and Medical Center

City
Qazvin

Province
Qazvin

Postal code
3464186699

Phone
+98 28 3379 0611

Email
dr.amirrezakhazzaei@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Tahereh Mahdavi

Position
General medicine student

Latest degree
A Level or less

Other areas of specialty/work
Internal Medicine

Street address
Qazvin, Minoodar, taavon Square, Provincial Educational and Medical Center

City
Qazvin

Province
Qazvin

Postal code
3464186699

Phone
+98 28 3379 0611

Email
dr.amirrezakhazzaei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Tahereh Mahdavi

Position
General medicine student

Latest degree
A Level or less

Other areas of specialty/work
Internal Medicine

Street address
Qazvin, Minoodar, taavon Square, Provincial

Educational and Medical Center

City
Qazvin

Province
Qazvin

Postal code
3464186699

Phone
+98 28 3379 0611

Email
dr.amirrezakhazzaei@gmail.com

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