# 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)
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**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**
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**Province**
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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

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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**
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

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## Person responsible for scientific inquiries

**Contact**

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**Position**
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**Latest degree**
A Level or less

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## Person responsible for updating data

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**Latest degree**
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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