Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the synergism effect of Xenogan capsule and Chlorella algae tablets with metformin and vitamin E in the treatment of patients with Non-alcoholic fatty liver - a single-blind randomized clinical trial

Protocol summary

Study aim

A comparative study of the synergism effect of Xenogan capsule and Chlorella algae tablets with metformin and vitamin E in the treatment of patients with Non-alcoholic fatty liver

Design

This is a randomized clinical trial that will be conducted as a parallel design and single-blinded; phases 2-3 will be conducted on 90 patients with non-alcoholic fatty liver disease. Random permutation blocks are used for randomization, and participants are assigned to three intervention groups.

Settings and conduct

This study, which will be conducted at Imam Khomeini Hospital of Kermanshah, is single-blinded. Patients will be kept blinded to the type of drug they receive. At the beginning of the study, liver ultrasound and fasting blood samples are performed for all patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Patients with fatty liver; High liver enzymes AST, ALT Exclusion criteria: Pregnancy or breastfeeding; being an alcoholic; History of biliary diseases, heart and blood vessels, liver diseases, kidney failure and bleeding peptic ulcer, types of cancer, thyroid

Intervention groups

In the first intervention group, 1000 mg metformin tablets and 400 units of vitamin E capsules (pharmaceutical company...) are prescribed daily for 12 month. In the second intervention group, two tablets (250 mg) of Zinogan capsules(Dorset Home Company) along with 1000 mg metformin tablets and 400 units of vitamin E capsules are prescribed daily for 12month. In the third intervention group, three tablets (900 units) of Algomed chlorella algae tablets along (Steinberg Bioproduct Company) with 1000 mg of metformin tablets and 400 units of vitamin E capsules are prescribed daily for 12month.

Main outcome variables

Liver enzymes (AST, ALT, ALP), Tri glyceride, Total cholesterol, Plasma insulin levels, Blood sugar, Bilirubin, Antioxidant level in blood serum, Serum albumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056221N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Mohammad Bagher Majnooni

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3427 6471

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-05-10, 1402/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the synergism effect of Xenogan capsule and Chlorella algae tablets with metformin and vitamin E in the treatment of patients with Non-alcoholic fatty liver - a single-blind randomized clinical trial

Public title

A comparative study of the synergism effect of Xenogan capsule and Chlorella algae tablets with metformin and vitamin E in the treatment of patients with Non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Patients with fatty liver (grade 1-3) High liver enzymes AST, ALT (more than 4-35 IU/L)

Exclusion criteria:

Pregnancy or breastfeeding being an alcoholic History of biliary diseases, heart and blood vessels, liver diseases, kidney failure and bleeding peptic ulcer, types of cancer, thyroid The presence of gastrointestinal ulcers Taking any herbal supplements and vitamins

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization will be done by the method of random permutation blocks using PASS 2011 software. In this way, using PASS 2011 software, in 15 permutation blocks, six members of the letters α β γ representing each of the treatment groups (for example αβγγβα) will be created by someone outside the research plan and will be placed in envelopes, then one of the envelopes will be randomly selected, and the task of the appointed groups of 6 people who will enter the study will be determined. This will continue until the full assignment of 90 patients to 3 study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst was kept blinded to the study group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.KUMS.MED.REC.1401.124

Health conditions studied

1

Description of health condition studied

non alcohlic fatty liver disease

ICD-10 code

K76

ICD-10 code description

Other diseases of liver

Primary outcomes

1

Description

Liver enzymes (AST, ALT, ALP)

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

2

Description

Tri glyceride

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

3

Description

Total cholesterol

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

4

Description

Plasma insulin levels

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

5

Description

Blood sugar

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

6

Description

Bilirubin

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

7

Description

Antioxidant level in blood serum

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

8

Description

Serum albumin

Timepoint

The beginning of the study and the end of the twelfth week

Method of measurement

Using a blood test

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, 1000 mg metformin tablets and 400 units of vitamin E capsules (pharmaceutical company...) are prescribed daily for 12 month.

Category

Treatment - Drugs

2

Description

In the second intervention group, two tablets (250 mg) of Zinogan capsules(Dorset Home Company) along with 1000 mg metformin tablets and 400 units of vitamin E capsules are prescribed daily for 12month.

Category

Treatment - Drugs

3

Description

In the third intervention group, three tablets (900 units) of Algomed chlorella algae tablets along (Steinberg Bioproduct Company) with 1000 mg of metformin tablets and 400 units of vitamin E capsules are prescribed daily for 12month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Shahab Bazvandi

Street address

Imam Khomeini Hospital, Naghliyeh street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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cjalili@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Shahab Bazvandi
Position
Resident of Internal
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available