

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of Afsanteen (*Artemisia Absinthium L.*) on liver functional indexes in patient with non alcoholic fatty liver disease

Protocol summary

Study aim

Evaluation of the effect of Afsanteen (*Artemisia Absinthium L.*) on liver functional indexes in patient with non alcoholic fatty liver disease

Design

This clinical trial was performed on 56 patients, divided into two groups of 28, including a control group and parallel groups. This study is Double-blind and block randomization method is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects over 18-20 years old who were diagnosed with non alcoholic fatty liver disease (NAFLD) by Sonography and increased levels of ALT and AST. Exclusion criteria: Alcohol consumption of more than 140cc in men and 70 cc in women per week, Patients with viral hepatitis, diabetes, Patients taking lipid-lowering drugs, Pregnancy and Lactation, Patients taking drugs affecting liver enzymes, Patients with autoimmune diseases, History of bleeding and hemostatic disorders, Patients taking anticoagulants, Patients with allergies to herbs and herbal medicines

Intervention groups

Patients in the intervention group, receive Afsantin Capsule in the form of 1200 mg capsules twice a day for three months and the control group also receives placebo according to the above method.

Main outcome variables

Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Alkaline Phosphatase (ALP); Gamma glutamine transferase (GGT) ; Bilirubin; Grade of fatty liver; Body Mass Index (BMI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N12**

Registration date: **2023-02-23, 1401/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**

Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 9435

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Afsanteen (Artemisia Absinthium L.) on liver functional indexes in patient with non alcoholic fatty liver disease

Public title

Effect of Afsanteen (Artemisia Absinthium L.) In Treatment of Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with aminotransferases greater than 1.5 times the normal maximumUltrasound images with Stage 2, 3 Ultrasound images with Stage 2, 3

Exclusion criteria:

Pregnancy Lactation Alcohol consumption (more than 140 cc in men and 70 cc in women per week) Viral hepatitis Diabetic patients Patients taking drugs that affect the liver enzymes Patients taking anticoagulants People with a history of bleeding and hemostatic disorders Patients with allergies to herbs and herbal remedies

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive Afsantin Capsule and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66117713446

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.MUK.REC.1401.381

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty liver

ICD-10 code

Fatty (cha

ICD-10 code description

K76.0

Primary outcomes

1

Description

Alanine Aminotransferase (ALT)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

2

Description

Aspartate Aminotransferase (AST)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

3

Description

Alkaline Phosphatase (ALP)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

4

Description

Gamma glutamine transferase (GGT)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

5

Description

Bilirubin

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

6

Description

Grade of fatty liver

Timepoint

At baseline and end of the study

Method of measurement

Sonography

7

Description

Body Mass Index (BMI)

Timepoint

At baseline and end of the study

Method of measurement

by measuring height and weight using a scale and height meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Afsantin capsule is taken as a 1200 mg soft capsule, manufactured by Bou Ali Daru

Company, twice a day for three months. The two study groups receive their respective standard treatment and follow-up. Both groups are advised to follow a suitable and low-fat diet.

Category

Placebo

2

Description

Control group: They receive the placebo in the form of 1200 mg capsules, twice a day for three months. The two study groups receive their respective standard treatment and follow-up. Both groups are advised to follow a suitable and low-fat diet.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Liver and Digestive Clinic of Tohid Hospital, Sanandaj

Full name of responsible person

Dr Farshad Sheikh esmaeili

Street address

Tohid Hospital, Tohid Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Afshin Maleki

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Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

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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
Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Dr Farshad Sheikhesmaeili

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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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