Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Study aim
Evaluation of the effect of Afsanteen (Artemisia Absinthium L.) on liver functional indexes in patient with non alcholic 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 alcholic 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
p.sharifi@muk.ac.ir

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 alcholic 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 Alcholic 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
City
Sanandaj
Province
Kurdistan
Postal code
6616813131
Phone
+98 87 3328 6112
Email
dr_s_smaili@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Afshin Maleki
Street address
Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.
City
Sanandaj
Province
Kurdistan
Postal code
6617713466
Phone
+98 87 3366 4645
Email
maleki43@yahoo.com

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
Street address
Tohid Hospital, Tohid Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Phone
+98 87 3366 4645
Email
dr_s_smaili@yahoo.com

Person responsible for scientific 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
Street address
Tohid Hospital, Tohid Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Phone
+98 87 3366 4645
Email
dr_s_smaili@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Pezhman Sharifi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Microbiology
Street address
Research Department, Tohid Hospital, Tohid Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6616813131
Phone
+98 87 3324 9435
Fax
+98 87 3324 9435
Email
p.sharifi@muk.ac.ir

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