

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effectiveness of the combination of atorvastatin and aspirin with atorvastatin alone on the severity of liver fibrosis in cirrhotic patients referred to Ali Bin Abi Taleb Hospital in2023-2025

Protocol summary

Study aim

Comparison of the effectiveness of the combination of atorvastatin and aspirin with atorvastatin alone on the severity of liver fibrosis in cirrhotic patients

Design

The trial with two parallel groups, randomized, phase 4, on 81 patients, is done for randomization from the table of random numbers to the form of information in a separate envelope.

Settings and conduct

The trial will be conducted in Ali Bin Abi Taleb Hospital. Liver cirrhosis patients who come to the clinic and meet the conditions to be included in the study will be treated by a gastroenterology specialist, a questionnaire will be filled out, and they will be visited after three months. Blinding is done by placing information in numbered envelopes

Participants/Inclusion and exclusion criteria

Patients with liver cirrhosis who were diagnosed with manifestations, age 18-75, sonography based on cirrhosis.

Intervention groups

Intervention group 1: atorvastatin and aspirin.
Intervention group 2: atorvastatin alone.

Main outcome variables

Quality of life; creatine kinase; liver enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231002059591N1**

Registration date: **2023-11-03, 1402/08/12**

Registration timing: **prospective**

Last update: **2023-11-03, 1402/08/12**

Update count: **0**

Registration date

2023-11-03, 1402/08/12

Registrant information

Name

Bahareh Mahjoubi asil

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5634

Email address

b.mahjoubi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of the combination of atorvastatin and aspirin with atorvastatin alone on the severity of liver fibrosis in cirrhotic patients referred to Ali Bin Abi Taleb Hospital in2023-2025

Public title

Investigating the effect of atorvastatin and aspirin on liver cirrhosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Patients with liver cirrhosis who were diagnosed with symptoms

Age 18-75
Ultrasound based on cirrhosis

Exclusion criteria:

- pregnant woman
- Statin use in the last year
- affected hcc
- LDL >70
- Myopathy caused by atherostatin treatment
- meld>23
- child pugh>13
- Evidence of infection in the last 4 weeks
- Hepatorenal syndrome in clinical and biochemical evidence in the last 14 days
- High hepatic encephalopathy 2-3 times increase of aminotransferase in 3 months after starting the study
- Recent use of febrat, varithromycin and others
- use P450 inhibitor
- Esophageal varices
- Patient dissatisfaction

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

4

Groups that have been masked

- Investigator

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Block of four will be used for each of the treatment groups. In this way, someone other than the doctor will determine the treatment block with the help of random numbers obtained from the computer. block therapy: AABC-ABBC-BBAC-BCCA-..... A; The group taking atorvastatin B: The group that takes atorvastatin and copper aspirin C: The group that does not take medicine

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding: on the one hand, the researcher is not aware of the type of intervention performed, and on the other hand, the doctor evaluating the outcome of the study is also aware of the type of treatment used. *Allocation concealment is done using "opaque sealed envelopes with random sequence". In this way, the random sequence is determined first, then the sequences are recorded on a card and the cards are placed in the envelopes in order. The outer surface of the envelopes is numbered and placed in the box in order. Participants will choose an envelope in order of entry and the intervention group will be determined

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan Medical Sciences

Street address

Hasabi Square - Imam Hossein Blvd - Zahedan Faculty of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Approval date

2023-08-20, 1402/05/29

Ethics committee reference number

IR.ZAUMS.REC.1402.260

Health conditions studied

1

Description of health condition studied

Toxic liver disease with fibrosis and cirrhosis of liver

ICD-10 code

K71.7

ICD-10 code description

Toxic liver disease with fibrosis and cirrhosis of liver

Primary outcomes

1

Description

CK: One of the body's muscle enzymes

Timepoint

Every three months to a year

Method of measurement

Measurements from the patient's blood sample

2

Description

AST :SGOT is an enzyme from the group of transferases. In fact, it is a PLP-dependent transaminase that is mainly found in the liver

Timepoint

Every three months to a year

Method of measurement

Measurements from the patient's blood sample

3

Description

It is an enzyme found mainly in the liver, but small amounts are also found in the kidneys, heart, muscles, and pancreas. (SGPT)

Timepoint

Every three months to a year

Method of measurement

Measurements from the patient's blood sample

4

Description

PT:Blood clotting time

Timepoint

Every three months to a year

Method of measurement

Measurements from the patient's blood sample

5

Description

PLT:The number of platelets in the serum

Timepoint

Every three months to a year

Method of measurement

Measurements from the patient's blood sample

Secondary outcomes

1

Description

Fib_4 index:Fibrosis index base on index-Non-invasive indicator of liver fibrosis

Timepoint

Every three months to a year

Method of measurement

It is calculated based on age and platelets and AST in the formula

2

Description

Non-invasive indicator of liver fibrosis-Ast to platlet retio index

Timepoint

Every three months to a year

Method of measurement

It is calculated based on AST and PLT in the formula

Intervention groups

1

Description

Intervention group: patients who are given atorvastatin 40 mg and aspirin 80 mg once a day for one year.

Category

Treatment - Drugs

2

Description

Intervention group: patients who were given only atorvastatin 40 mg once a day for one year

Category

Treatment - Drugs

3

Description

Control group: Patients who do not receive any medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Bin Abi Talib Hospital

Full name of responsible person

Bahareh Mmahjoubi Asil

Street address

Persian Gulf Square - Shahid Mir Boulevard - Ali Bin Abi Talib Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5574

Email

info@sbmu.ac.ir

Web page address

<https://alihos.zaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Bahareh Mahjoubi Asil

Street address

Hasabi Square - University Blvd - Islamic Azad University - Zahra Dormitory

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167743545

Phone

+98 54 3341 9431

Email

baharhmahjoubi@gmail.com

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Private

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

Zahedan University of Medical Sciences

Full name of responsible person

Bahareh Mahjoubi Asil

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Hasabi Square - University Blvd - Islamic Azad
University - Zahra Dormitory

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743545

Phone

+98 54 3341 9431

Email

baharehmahjoubi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Bahareh Mahjoubi Asil

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Hasabi Square - University Blvd - Islamic Azad
University - Al Zahr Dormitory

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743545

Phone

+98 54 3341 9431

Email

baharehmahjoubi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Bahareh Mahjoubi Asil

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Hasabi-square--University-boulevard---Islamic-Azad-
University---Al-Zahra-dormitory

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743545

Phone

+98 54 3341 9431

Email

baharehmahjoubi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be published without publishing the identity
of the patients

When the data will become available and for how long

Access to data is six months after printing the results

To whom data/document is available

Researchers who are in scientific and academic
institutions

Under which criteria data/document could be used

If the patient consents

From where data/document is obtainable

bahareh mahjoubi asil baharehmahjoubi@gmail.com

What processes are involved for a request to access data/document

Providing proof of being a researcher in academic and

scientific institutions by email to
baharehmahjoubi@gmail.com

Comments