Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 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)
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+98 54 3329 5634
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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 Hepatornal 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 febrate, varithromycin and others useP450 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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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

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

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Person responsible for updating data

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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