

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of exercise versus control group on cardiac inflammatory factors in patients with liver disease: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of exercise versus control group on cardiac inflammatory factors in patients with liver disease

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct

This study will be performed in the Islamic Azad University in Hamadan city on 30 eligible patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years Liver failure
Exclusion criteria: Diabetes, asthma or cardiovascular diseases Using tobacco, drugs, alcohol, or stimulants

Intervention groups

Intervention group: Routine care of liver patients in addition to resistance exercises (including squat, chest press, barbell launch, front cable pull bar, abdominal crunch, barbell under chest) with an intensity of 60% to 80% for 1.5 hours a week, three sessions for 8 weeks.
Control group: Follow-up and routine care only.

Main outcome variables

Primary outcome: Cardiac inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N444**
Registration date: **2022-10-12, 1401/07/20**
Registration timing: **prospective**

Last update: **2022-10-12, 1401/07/20**

Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of exercise versus control group on cardiac inflammatory factors in patients with liver disease: a randomized clinical trial

Public title

Effect of exercise versus control group on cardiac inflammatory factors in patients with liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Liver failure

Exclusion criteria:

Diabetes, asthma or cardiovascular diseases Using tobacco, drugs, alcohol, or stimulants

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Khomeini Ave.

Street address

Vice-chancellor for Research and Technology, Islamic Azad University, Khomeini Ave.

City

Hamadan

Province

Hamadan

Postal code

6518115743

Approval date

2022-08-28, 1401/06/06

Ethics committee reference number

IR.IAU.H.REC.1401.030

Health conditions studied

1

Description of health condition studied

Liver disease

ICD-10 code

K77

ICD-10 code description

Liver disorders in diseases classified elsewhere

Primary outcomes

1

Description

Cardiac inflammatory factors

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

By laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care of liver patients in addition to resistance exercises (including squat, chest press, barbell launch, front cable pull bar, abdominal crunch, barbell under chest) with an intensity of 60% to 80% for 1.5 hours a week, three sessions for 8 weeks.

Category

Treatment - Other

2

Description

Control group: Follow-up and routine care only.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University in Hamadan city

Full name of responsible person

Ahmad Fili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Islamic Azad University
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

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Person responsible for updating data

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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