

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

##### Street address

Islamic Azad University, Khomeini Ave.

##### City

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Dr. Mansour Esmaeilpour  
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Islamic Azad University, Khomeini Ave.  
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esmaeilpour@iauh.ac.ir  
**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

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ahmad Fili  
**Position**  
Student of Sport Physiology  
**Latest degree**  
Master  
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Sport Medicine  
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Islamic Azad University, Khomeini Ave.

#### Person responsible for scientific inquiries

##### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Dr. Javad Almasi  
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Sport Physiologist  
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#### Person responsible for updating data

##### Contact

**Name of organization / entity**  
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**Position**  
Professor of Epidemiology  
**Latest degree**  
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**Other areas of specialty/work**  
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**Email**

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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