

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The assessment effect of aerobic training program on serum transaminases' levels and quality of life in patients with Non-Alcoholic Steatohepatitis

#### Protocol summary

##### Summary

The purpose of this study program of aerobic exercise on serum transaminase and trace is the quality of life in patients with alcoholic steatohepatitis. Thirty NASH patients with the range of age 18 to 65 years old that randomly they were divided in two groups of diet (n=15) and aerobic training with diet (n=15). Patients with inclusion criteria: 1 - 18 to 65 years 2 - Approval Kbdchrb ultrasound 3 - Increase 5 / 1 Equity serum enzyme alanine aminotransferase (ALT) and Exclusion criteria: 1 - Hepatitis B2-hepatitis C 3 - autoimmune hepatitis 4 - CD 5 - Wilson 6 - 1 $\alpha$ -deficient anti  $\rightarrow$  trypsin 7 - Hemochromatosis 8 - 9 thyroid disease - ischemic heart disease 10 - 11 of kidney failure - drugs Hpatvtvksyk 12 - more than 20 grams of alcohol per day were enrolled. Anthropometric indices, serum liver enzymes and biochemical factors were evaluated before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104286319N1**  
Registration date: **2011-08-27, 1390/06/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-08-27, 1390/06/05

##### Registrant information

##### Name

Hamidreza Sima

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1843 3363

##### Email address

simahr@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2010-04-04, 1389/01/15

##### Expected recruitment end date

2010-09-22, 1389/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The assessment effect of aerobic training program on serum transaminases' levels and quality of life in patients with Non-Alcoholic Steatohepatitis

##### Public title

The Effect of Exercise and nutrition on fatty liver disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 18 to 65 years ; Approval Kbdchrb ultrasound; Increase 1.5 Equity serum enzyme alanine aminotransferase. Exclusion criteria: Hepatitis B2; Hepatitis C; Autoimmune hepatitis; CD; Wilson; 1 $\alpha$ -deficient anti-trypsin; Hemochromatosis; thyroid disease; Ischemic heart disease; kidney failure; Drugs Hpatvtvksyk; More than 20 grams of alcohol per day.

**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****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**

Mashhad University of Medical Sciences

**Street address**

School of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square

**City**

Mashhad

**Postal code**

9177948564

**Approval date**

2011-03-12, 1389/12/21

**Ethics committee reference number**

89878

**Health conditions studied****1****Description of health condition studied**

Non Alcoholic Steatohepatitis

**ICD-10 code**

K70-K77

**ICD-10 code description**

Diseases of liver

**Primary outcomes****1****Description**

ALT

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

Unit U / L, a photometer methods

**2****Description**

AST

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

Unit U / L, a photometer methods

**3****Description**

FBS

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

mg/dL

**4****Description**

Insulin

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

mIU/mL

**5****Description**

Chol

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

mg/dL

**6****Description**

LDL

**Timepoint**

Before the intervention, two months after the start and end of three months

**Method of measurement**

mg/dL

**7****Description**

HDL

**Timepoint**

Before the intervention, two months after the start and

end of three months  
**Method of measurement**  
mg/dL

## **8**

**Description**  
VLDL  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
mg/dL

## **9**

**Description**  
TG  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
mg/dL

## **10**

**Description**  
Weight  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
gram

## **11**

**Description**  
BMI  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
Kg/M2

## **12**

**Description**  
WC  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
Cm

## **13**

**Description**  
WHpR  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
%

## **14**

**Description**  
WHtR  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
%

## **15**

**Description**  
HC  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
Cm

## **16**

**Description**  
PBF  
**Timepoint**  
Before the intervention, two months after the start and end of three months  
**Method of measurement**  
Body Composition

## **17**

**Description**  
Quality of life  
**Timepoint**  
before and after intervention  
**Method of measurement**  
SF-36 Standard questionnaire

## **Secondary outcomes**

### **1**

**Description**  
Height  
**Timepoint**  
Before the intervention, two months later and after three months  
**Method of measurement**  
Cm

## **Intervention groups**

### **1**

**Description**  
Diet with aerobic training program  
**Category**  
Treatment - Devices

### **2**

**Description**

Diet alone  
**Category**  
Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Center of Liver researches, Department of Internal Hospital, Imam Reza Mashhad

**Full name of responsible person**

Dr Hamid Reza Sima

**Street address****City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Hamid Reza Sima

**Street address**

School of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Nematy

**Position**

Assistant Professor in Clinical Nutrition

**Other areas of specialty/work****Street address**

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**Fax****Email**

NematyM@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Hamid reza Sima

**Position**

Advanced Hepatology Fellowship

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Ferdowsi University of Mashhad

**Full name of responsible person**

Hossein Nikroo

**Position**

MA

**Other areas of specialty/work****Street address**

No 19, 11th Emamat, Emamat Boulevard

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Mashhad

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+98 51 1605 4628

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Gym.hnikroo@gmail.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*