

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of Aerobic exercise with Whole-Body vibration versus Aerobic exercise alone in Non-Alcoholic Fatty Liver diseases

Protocol summary

Summary

The main aim of this study is to compare the effects of Aerobic exercise along with Whole-Body vibration, versus Aerobic exercise alone, on Bio-chemicals of Non-Alcoholic Fatty Liver patients. This is a randomized, interventional clinical trial. Inclusion criteria: Non Alcoholic Fatty liver disease grade I and II, which is diagnosed in ultrasound imaging; BMI= 27-35 Exclusion criteria: Alcohol intake> 5 units/weak; Hepatotoxic drugs; Other exercise contraindication such as Cardiopulmonary disease or Musculoskeletal problems. Sampling Method: Simple sampling. Sample Quantity: 32 Patients. Gastrointestinalologist will refer 32 patients one by one and then, Lipid profiles and Liver enzymes, as primary outcomes for all patients will be tested and divided into two groups randomly. Intervention group will be placed under 5minutes of Whole-Body vibration and then Aerobic exercises, for 24 sessions, 40minutes each, whereas, the Control group will be placed under Aerobic exercises only, for 24 sessions, 40minutes each. Finally Lipid profiles and Liver enzymes for both groups will be tested and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604162664N3**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Yaghoob Salekzamani

Name of organization / entity

Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3967

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Aerobic exercise with Whole-Body vibration versus Aerobic exercise alone in Non-Alcoholic Fatty Liver diseases

Public title

Effects of the Whole-Body vibration, in Non-Alcoholic Fatty Liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non Alcoholic Fatty liver disease grade I and II, which is diagnosed in ultrasound imaging; BMI= 27-35 Exclusion criteria: Alcohol intake> 5 units/weak; Hepatotoxic drugs such as Amiodaron, Tomoxifen, MTX, Fibrat or others; Exercise contraindications such as

Cardiopulmonary disease or Musculoskeletal problems.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

tbzmed.rec.1394.37

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K75.8, K76

ICD-10 code description

Nonalcoholic steatohepatitis (NASH), Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description

Lipid Profile (TG, Chol, LDL, HDL)

Timepoint

Before and after intervention

Method of measurement

Biochemical laboratory

2

Description

Liver Enzyme (ALP, ALT, AST)

Timepoint

Before and after intervention

Method of measurement

Biochemical laboratory

Secondary outcomes

1

Description

Weight, height, waist to hip ratio, fat mass, lean body mass, BMI

Timepoint

Before and after intervention

Method of measurement

Body Composition Analyzer

Intervention groups

1

Description

Control group: 40 min (3 days/week) aerobic exercise for 8 weeks

Category

Treatment - Other

2

Description

Intervention group: 8 weeks (3 days/week) aerobic exercise, duration 40 min with 5 min whole body vibration before exercise

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadi medical clinic

Full name of responsible person

Dr. Manouchehr khoshbaten, gastroenterologist, professor of university

Street address

Sixth floor, Azadi medical clinic, Aazadi street, Tabriz

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rooya Dolatkhan

Street address

Physical medicine and Rehabilitation center,
Emamreza hospital, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Physical medicine and Rehabilitation group of Tabriz
University of Medical Sciences

Full name of responsible person

Dr. Morteza Haghverdi

Position

Resident of Physical medicine and Rehabilitation

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Physical Medicine and Rehabilitation center of Tabriz
University of Medical Sciences

Full name of responsible person

Yaghob Salekzamani

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Morteza Haghverdi

Position

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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