

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Improved fatty liver index- induced high-intensity interval training associated with decrease liver enzyme plasma levels and metabolic parameters in type 2 diabetes

Protocol summary

Study aim

The aim of this study was to investigate the effect of High Intensity Interval Training (HIIT) on the improvement of fatty liver biomarkers associated with reduced liver enzymes and metabolic parameters in type 2 diabetes.

Design

The present study is a double-blind randomized clinical trial . 40 patients are divided into intervention and control groups. The intervention group uses HIIT exercise in addition to general therapies. Excel software rand function was used for randomization. Due to the lack of drug interventions, the term "phase" is not applicable to the present study.

Settings and conduct

Participants received their intervention in groups. The location of the project is Loghman Hakim Hospital. Blood samples are collected 24 hours before exercise and 48 hours after interventions. At the beginning of the research, a code will be assigned to each subject and in all subsequent steps, the code will be used instead of the names of the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients of Loghman Hakim Hospital age limit (45 to 60 years) Male weight. A1C more than 6% Exclusion criteria: Neuromuscular diseases, Nephropathy, Hypertension, Myocardial infarction and Bypass surgery

Intervention groups

The control group of the subjects of this group will not have any regular sports activities and will receive only the usual hospital treatments. The intervention group of subjects in this group will perform three sessions per week of HIIT training with 80% of maximum heart rate for 4 weeks.

Main outcome variables

Lipid profile, glycemic index, liver enzymes and renal

function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200729048246N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

hoseyn fatolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7628 1010

Email address

hoseyn.fatolahi@pardisau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-01, 1398/02/11

Expected recruitment end date

2019-06-01, 1398/03/11

Actual recruitment start date

2019-06-02, 1398/03/12

Actual recruitment end date

2019-07-02, 1398/04/11

Trial completion date

2020-09-02, 1399/06/12

Scientific title

Improved fatty liver index- induced high-intensity interval training associated with decrease liver enzyme plasma levels and metabolic parameters in type 2 diabetes

Public title

Response of metabolic parameters to 4 weeks of High Intensity Interval Training (HIIT)

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetic patients of Loghman Hakim Hospital A1C more than 6% Lack of Orthopedic diseases Age limit (45 to 60 years) male and female lack of neuromuscular disease lack of Nephropathy lack of Hypertension lack of Myocardial infarction lack of Bypass surgery

Exclusion criteria:

Orthopedic diseases neuromuscular disease Nephropathy Hypertension Myocardial infarction Bypass surgery

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a computer and simple randomization. The software randomly selects numbers between 1 and 0 and numbers less than 0.5 will be in the control group and numbers greater than 0.5 will be in the intervention group. Finally, 40 subjects will be divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects were coded instead of using their names. From an uninformed person Was asked to randomly distribute the codes. Study groups instead The group name had a code. Laboratory of the names of groups and participants was informed and used codes. Codes were also used for statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Loghman Hakim clinical research development center

Street address

Kargar South Kamali St. Loghman Hakim Medical and Educational Center Clinical Research Development Center

City

Tehran

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Postal code

1333631151

Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.187

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

Type 2 diabetes

ICD-10 code**ICD-10 code description**

Type 2 diabetes

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

liver enzyme plasma levels

Timepoint

24 hours before the intervention period and 48 hours after the intervention period

Method of measurement

ELISA

Secondary outcomes**1****Description**

Fatty liver index

Timepoint

24 hours before the intervention period and 48 hours after the intervention period

Method of measurement

Fatty liver index (FLI) is a non-invasive method for assessing hepatic steatosis which calculated by following formula: $FLI = (e^{0.953} \times \log_e(\text{triglycerides}) + 0.139 \times BMI + 0.718 \times \log_e(\text{GGT}) + 0.053 \times \text{waist circumference} - 15.745) / (1 + e^{0.953} \times \log_e(\text{triglycerides}) + 0.139 \times BMI + 0.718 \times \log_e(\text{GGT}) + 0.053 \times \text{waist circumference} - 15.745) \times 100$. The FLI was calculated in each subjects.

2

Description

Lipid profile

Timepoint

24 hours before the intervention period and 48 hours after the intervention period

Method of measurement

ELISA

3

Description

HbA1c

Timepoint

24 hours before the intervention period and 48 hours after the intervention period

Method of measurement

ELISA

4

Description

Renal function, measurement of urea and creatinine

Timepoint

24 hours before the intervention period and 48 hours after the intervention period

Method of measurement

Quantified by photometry

Intervention groups

1

Description

All of the participants conducted supervised HIIT on cycling ergometer (894E Monark Ergomedic Peak Bike, Varberg, Sweden) three sessions per week for 4- weeks. Each session of HIIT consisted of 4-intervals (1 min) at 80% maximal heart rate (HRmax) separated by 4 min at 70% HRmax. Each training session was start by 5 min of warm-up, which including walking, running and stretching movements at 40% HRmax. The participants ended the session of exercise training with 5 min at 40% HRmax as cool-down. To ensure appropriate intensity, all patients wore a heart rate monitor (Polar Beat, Polar Electro) during each exercise session.

Category

Lifestyle

2

Description

Control group: The subjects in this group will not have any regular exercise and will only use the usual treatments for type 2 diabetes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Educational Medical Center

Full name of responsible person

Dr Saeed Kalbasi

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<http://www.sbmu.ac.ir/sitedirectory/loghmanHakim>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Saeed Kalbasi

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<http://en.sbu.ac.ir/Vicepresidencies/Research%20and%20Technology%20Vice/Pages/default.aspx>

Grant name

Vice-presidency for Research and Technology of Shahid Beheshti University of Medical Sciences

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Diseases

Latest degree

Ph.D.

Other areas of specialty/work

Emergency Medicine

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Saeed Kalbasi

Position

Vice President of the Diabetes Association and Chairman of the Loghman Hospital Infectious Diseases

Latest degree

Ph.D.

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Saeed Kalbasi

Position

Vice President of the Diabetes Association and Chairman of the Loghman Hospital Infectious Diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Saeed Kalbasi

Position

Vice President of the Diabetes Association and Chairman of the Loghman Hospital Infectious

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data of research dependent variables can be coded without the name of the subject Release

When the data will become available and for how long

The article will be available after submission

To whom data/document is available

researchers

Under which criteria data/document could be used

The data are available for re-analysis by researchers

From where data/document is obtainable

Author.

What processes are involved for a request to access data/document

The request should be sent by email to the responsible author.

Comments