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 indexe, 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

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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

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Tehran

Province
Tehran

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 × loge (triglycerides) + 0.139 × BMI + 0.718 × loge (GGT) + 0.053 × waist circumference – 15.745)/ (1 + e 0.953 × loge (triglycerides) + 0.139 × BMI + 0.718 × loge (GGT) + 0.053 × waist circumference – 15.745) × 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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

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
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Other areas of specialty/work
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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