

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of resistance training with and without blood flow restriction on the serum levels of sirtuin1 and nitric oxide in patients with type2 diabetes

Protocol summary

Study aim

Determining the effect of resistance training with and without blood flow restriction on the serum levels of sirtuin 1 and nitric oxide in patients with type 2 diabetes.

Design

A clinical trial with a control group, factorial, randomized with random computer software

Settings and conduct

At first, the blood samples of the people in the three groups will be taken by a specialized expert before the start of the first day of training in fasting conditions. The participants in the two groups of resistance training with and without blood flow restriction will have three training sessions per week, and then in At the end of the intervention, blood sampling will be repeated again under the same conditions as the pre-test

Participants/Inclusion and exclusion criteria

Inclusion criteria: 45 men with type 2 diabetes aged 40 to 60 years, not taking insulin, and not exercising in the past year. Exclusion criteria: regularly participating in exercises, muscle damage and knee and hip joint damage, having heart disease and high blood pressure.

Intervention groups

Resistance training group with blood flow restriction where people will have the usual and traditional way of training, Resistance training group without blood flow restriction where people will train using pressure and control group of people who will not receive any exercise.

Main outcome variables

Serum level of sirtuin 1; serum level of nitric oxide; blood pressure level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241004063256N1**

Registration date: **2024-11-24, 1403/09/04**

Registration timing: **prospective**

Last update: **2024-11-24, 1403/09/04**

Update count: **0**

Registration date

2024-11-24, 1403/09/04

Registrant information

Name

Mahdiyeh Fatehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3351 8210

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-01-04, 1403/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of resistance training with and without blood flow restriction on the serum levels of sirtuin1 and nitric

oxide in patients with type2 diabetes

Public title
Investigating the effect of resistance training with and without blood flow restriction in type 2 diabetes

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 40 to 60 years History of type 2 diabetes for more than one yaer Not consuming insulin No history of sports activity in the past year
Exclusion criteria:
Having heart disease and high blood pressure Smoking Not participating regularly in training session

Age
From **40 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The number of 45 diabetic patients eligible to participate in the study by non-probability sampling method (easy and accessible) and based on the purpose of selection and randomly divided into three equal groups: resistance training with blood flow restriction, resistance training without blood flow restriction and control will be divided. A table of random numbers will be used for randomization.

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

Group work/ Ethics committee in research of University of Sistan and Baluchistan

Street address

Daneshgah blvd.

City

Zahedan

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Sistan-va-Balouchestan
Postal code
9816745845
Approval date
2023-11-14, 1402/08/23
Ethics committee reference number
IR.USB.REC.1402.023

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Serum level of sirtuin 1

Timepoint

Before the start of the intervention/16 weeks after the start of the intervention

Method of measurement

Measurement of sirtuin 1 concentration by ELISA method

Secondary outcomes

1

Description

Serum nitric oxide levels

Timepoint

Before the start of the intervention/16 weeks after the start of the intervention

Method of measurement

Using the ELISA method

2

Description

Blood pressure measurement

Timepoint

before and after each training session regularly during 16 weeks of intervention

Method of measurement

Using a digital sphygmomanometer

Intervention groups

1

Description

Intervention group: resistance exercise group with blood flow restriction; This group will perform the exercises in four sets with 15, 15, 15, 30 repetitions and 20% 1RM

intensity. Limitation of blood flow in the proximal part of the thigh and arm with the limiting cuff is continuously applied and during the rest between the sets, the blood flow limitation with the cuff will be removed.

Category

Prevention

2**Description**

Intervention group: resistance training group without blood flow restriction; This group will perform the exercises in four sets with 8-12 repetitions and an intensity of 80% of 1RM

Category

Prevention

3**Description**

Control group: This group will not receive any medicine or sports intervention and will continue their normal life.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Bin Abitalib Zahedan Hospital

Full name of responsible person

Dr. Shila Nayebifar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

Sistan and Baluchistan University Research Assistant

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

Yes

Title of funding source

The University of Sistan and Baluchistan

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**

University of Sistan and Baluchistan

Full name of responsible person

Mahdiyeh Fatehi

Position

Master's student in exercise physiology and health

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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

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Position

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Person responsible for updating data

Contact

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The University of sistan and baluchistan
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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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Subjects' information will be provided to other researchers after de-identification

When the data will become available and for how long

After the publication of the final research report

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Citing the findings by citing the source

From where data/document is obtainable

Mahdiyeh Fatehi/ mahdiyehfatehi2@gmail.com

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

The request will be sent to the given postal address or Mahdia Fathi's email and after the approval of the research team members, the data will be sent

Comments