

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 Aspersin and TNF- α 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 asprosin and TNF- α 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

45 men with type 2 diabetes/age 40 to 60 years old, no insulin use, no history of exercise in the past year, no regular participation in exercises, muscle damage and knee and hip joint damage, 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, control group of people who will not receive any exercise.

Main outcome variables

Asprosin serum level TNF- α serum level fat percentage

General information

Reason for update

Acronym

type 2 diabetes

IRCT registration information

IRCT registration number: **IRCT20240622062207N1**

Registration date: **2024-06-27, 1403/04/07**

Registration timing: **prospective**

Last update: **2024-06-27, 1403/04/07**

Update count: **0**

Registration date

2024-06-27, 1403/04/07

Registrant information

Name

Negin Abbaszadeh Bazzi

Name of organization / entity

University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

Phone

+98 54 3328 3605

Email address

neginabbaszadeh@pgs.usb.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-03, 1403/04/13

Expected recruitment end date

2024-08-03, 1403/05/13

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 Aspersin and

TNF- α in patients with type2 diabetes

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40 to 60 years Not taking insulin No history of sports activity in the past year

Exclusion criteria:

Lack of regular participation in exercises Muscle damage and knee and hip joint damage Having heart disease and high blood pressure

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

by computer random selection program

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

Working Group/Committee of Ethics in Research of University of Sistan and Baluchistan

Street address

University blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745845

Approval date

2023-11-14, 1402/08/23

Ethics committee reference number

IR.USB.REC.1402.022

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

Asprosin serum level

Timepoint

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

Method of measurement

Measuring asprosin concentration by ELISA method

Secondary outcomes

1

Description

TNF- α serum level

Timepoint

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

Method of measurement

Using the ELISA method

2

Description

fat percentage

Timepoint

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

Method of measurement

Using the wind composition device

Intervention groups

1

Description

Intervention group: Intervention group: resistance group with blood flow restriction

Category

Prevention

2

Description

Intervention group: Intervention group: resistance group without blood flow restriction

Category

Prevention

3

Description

Control group: Control group: no training group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital, Zahedan

Full name of responsible person

Dr.Shila Nayeibifar

Street address

University blvd

City

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Province

Sistan-va-Balouchestan

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Phone

+98 54 3113 6766

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shila_nayebifar@ped.usb.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Sistan and Baluchestan

Full name of responsible person

Dr.Shila Nayeibifar

Street address

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Postal code

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+98 54 3113 6766

Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Sistan and Baluchestan

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 Baluchestan

Full name of responsible person

Negin Abbaszadeh Bazzi

Position

Master's student in sports physiology and health

Latest degree

Bachelor

Other areas of specialty/work

Physiology

Street address

26Zlborz Street,Zahedan,Zibashahr

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Sistan and Baluchestan

Full name of responsible person

Dr.Nayeibifar

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Physiology

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City

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Person responsible for updating data

Contact

Name of organization / entity

University of Sistan and Baluchestan

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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

Negin Abbaszadeh Bazzi neginabbaszadeh@pgs.usb.ac.ir

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

The request will be sent to the given postal address or Negin Abbaszadeh Bazzi email, and the data will be sent after the approval of the research team members.

Comments