Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Investigation of TCF7L2 gene expression following aerobic exercise with and without blood occlusion in white blood cells of type 2 diabetes patients

Protocol summary

Study aim
Determination of TCF7L2 gene expression following aerobic exercise with and without blood occlusion in white blood cells of type 2 diabetes patients

Design
45 male patients with type 2 diabetes, aged 40 to 60 years and weighing (51.2±5.9), were randomly divided into three groups: aerobic exercise (n=15), aerobic exercise with blood flow obstruction (n=15), and control (n=15). Subjects in the aerobic exercise group and the aerobic exercise with blood flow obstruction group exercised 3 sessions per week for 16 weeks at an intensity of 50 to 65% of maximum heart rate, and subjects in the blood flow obstruction group exercised at a pressure of 30 to 60%. Blood sampling was also performed in two stages before and after the test after 10-12 hours of overnight fasting, and Real-Time PCR was used to measure gene expression. The results were analyzed using SPSS version 26 software and one-way ANOVA and Tukey's post hoc test.

Settings and conduct
The primary blood samples of all groups will be taken after fasting before the first session of training. The participants in the training groups will have 3 sessions of training in a week, running on the treadmill with and without blood restriction in the thigh area then all sampling will be repeated after 16 weeks similar to pre test

Participants/Inclusion and exclusion criteria
Entry criteria Age range of 40 to 60 years - male gender - having the ability to do sports Non-entry criteria Insulin consumption - presence of severe respiratory and heart failure - chronic disease of unknown origin - hepatitis - cancer - use of food supplements - motor impairment

Intervention groups
The group of aerobic exercises with blood flow restriction, the participants in this group, the group of aerobic exercises without blood flow restriction, the participants in the control group, people who did not do any exercise.

Main outcome variables
TCF7L2 gene expression

General information

Reason for update

Acronym
Type 2 diabetes

IRCT registration information
IRCT registration number: **IRCT20240125060808N1**
Registration date: **2025-03-02, 1403/12/12**
Registration timing: **retrospective**

Last update: **2025-03-02, 1403/12/12**
Update count: **0**

Registration date
2025-03-02, 1403/12/12

Registrant information

Name
Mina Rigi

Name of organization / entity
University of Sistan and Baluchestan

Country
Iran (Islamic Republic of)

Phone
+98 54 3323 0728

Email address
rigimina74@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-19, 1402/01/30

Expected recruitment end date
2023-06-20, 1402/03/30
Actual recruitment start date
2023-04-19, 1402/01/30
Actual recruitment end date
2023-06-22, 1402/04/01
Trial completion date
2023-10-23, 1402/08/01

Scientific title
Investigation of TCF7L2 gene expression following aerobic exercise with and without blood occlusion in white blood cells of type 2 diabetes patients

Public title
Investigating the effect of aerobic exercise with and without blood occlusion in type 2 diabetes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
History of type 2 diabetes for more than one year Not consuming insulin Age 40 to 60 years
Exclusion criteria:
Having a heart problem Not participating regularly in training session Smoking Not following health protocols
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: **100**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified random selection: Patients are stratified by certain characteristics, such as age, sex, or health status, and then randomly selected from each stratum.
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 Sistan and Baluchistan University (Research Ethics Committee)
Street address
Zahedan, University Blvd., Central Organization of Sistan and Baluchistan University, Shahid Qasim Mir Hosseini Building
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
۹۸۱۶۷-۴۵۸۴۵
Approval date
2023-04-09, 1402/01/20
Ethics committee reference number
IR.USB.REC.1402.008

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the primary outcome is "tcf7l2 gene (Transcription Factor 7-like 2) with the relative measure of fold unit".
Timepoint
In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients", the time points of tcf7l2 measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.
Method of measurement
In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel blockage in white blood cells of type 2 diabetes patients", the method of measuring the variable " real-time polymerase chain reaction

Secondary outcomes

1

Description
In the study "Investigation of TCF7L2 gene expression

following aerobic exercise with and without blood vessel blockage in white blood cells of type 2 diabetes patients" secondary outcome of fasting blood sugar in mg/dL units.

Timepoint

In the study "Examination of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the time points of fasting blood sugar measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure fasting blood sugar using Delta kit and biochemistry autoanalyzer of Biotecnica brand BT3500

2

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" is the secondary outcome of blood urea nitrogen with units of mg/dL.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients", the time points of blood urea nitrogen measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in the white blood cells of type 2 diabetes patients," how to measure blood urea nitrogen using the Delta Kit and the Biotecnica biochemistry autoanalyzer, model BT3500.

3

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" secondary outcome of blood creatinine in mg/dL unit.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" time points of blood creatinine measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blockage of blood vessels in the white blood cells of type 2 diabetes patients" how to measure blood creatinine using Delta kit and Biotecnica biochemistry autoanalyzer model BT3500

4

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel blockage in white blood cells of type 2 diabetes patients" is the secondary outcome of cholesterol in mg/dL units.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel blockage in white blood cells of type 2 diabetes patients" the time points of cholesterol measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in the white blood cells of type 2 diabetes patients" How to measure cholesterol "using the Delta kit and Biotecnica biochemistry autoanalyzer model BT3500"

5

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" is the secondary outcome of alkaline phosphatase with units of mg/dL.

Timepoint

In the study "Examination of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the time points of alkaline phosphatase measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure alkaline phosphatase" using the Delta kit and Biotecnica biochemistry autoanalyzer model BT3500"

6

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel

occlusion in white blood cells of type 2 diabetes patients" is the secondary outcome of aspartate aminotransferase with the criterion of units per liter.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the time points of aspartate aminotransferase measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in the white blood cells of type 2 diabetes patients" how to measure aspartate aminotransferase" using Delta kit and Biotecnica biochemistry autoanalyzer model BT3500"

7

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the secondary outcome of alanine aminotransferase with the criterion of units per liter.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients", the time points of measuring alanine aminotransferase of all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in the white blood cells of type 2 diabetes patients" how to measure alanine aminotransferase using the Delta kit and Biotecnica biochemistry autoanalyzer model BT3500

8

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the secondary outcome of triglycerides in mg/dL units.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel obstruction in white blood cells of type 2 diabetes patients" the time points of triglyceride measurement of all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure triglycerides using Delta kit and biochemistry autoanalyzer of Biotecnica brand BT3500

9

Description

In the study "Examination of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" secondary outcome of high density lipoprotein in mg/dL unit.

Timepoint

In the study "Examination of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" time points of high density lipoprotein measurement in all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure high density lipoprotein "using a biorex kit and a Biotecnica biochemistry autoanalyzer model BT3500"

10

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in the white blood cells of type 2 diabetes patients" is the secondary outcome of low-density lipoprotein in mg/dL units.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the time points of measuring low density lipoprotein of all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure low-density lipoprotein" using a biorex kit and Biotecnica biochemistry autoanalyzer model BT3500"

11

Description

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" is the secondary outcome of glycosylated hemoglobin with percentage units.

Timepoint

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" the time points of measuring glycosylated hemoglobin of all groups including the control group, the aerobic exercise group with blood flow obstruction and the aerobic exercise group without blood flow obstruction before the pre-test and 48 hours after the last exercise session at the end of the study.

Method of measurement

In the study "Investigation of TCF7L2 gene expression following aerobic exercise with and without blood vessel occlusion in white blood cells of type 2 diabetes patients" how to measure glycosylated hemoglobin using Pishtaz kit and Biotecnica biochemistry autoanalyzer model BT3500

Intervention groups

1

Description

Intervention group: low to moderate intensity treadmill running aerobic exercises with blood vessel occlusion using the Anhuma company device for 3 sessions a week for 16 weeks.

Category

Prevention

2

Description

Intervention group: Intervention group: low to moderate intensity treadmill running aerobic exercises without blood vessel occlusion for 3 sessions a week for 16 weeks.

Category

Prevention

3

Description

Control group: Not doing any physical activity and occlusion blood flow

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital

Full name of responsible person

مینا ریگی

Street address

Nurse 13

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816985819

Phone

+98 54 3323 0725

Email

rigimina74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Sistan and Baluchestan

Full name of responsible person

Sheila Naibifar

Street address

University blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745845

Phone

+98 54 3113 6766

Email

shila_nayebifar@ped.usb.ac.ir

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

Mina Rigi

Position

invited

Latest degree
Bachelor
Other areas of specialty/work
Applied exercise physiology
Street address
Nurse Blvd. between Nurse 11 and 13
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816985819
Phone
+98 54 3323 0725
Email
mina.rigi.usb@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Mina Rigi
Position
invited
Latest degree
Bachelor
Other areas of specialty/work
Applied exercise physiology
Street address
Nurse Blvd. between Nurse 11 and 13
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816985819
Phone
+98 54 3323 0725
Email
mina.rigi.usb@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Mina Rigi
Position
invited
Latest degree
Bachelor
Other areas of specialty/work
Applied exercise physiology
Street address
Nurse Blvd. between Nurse 11 and 13
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816985819
Phone
+98 54 3323 0725
Email
mina.rigi.usb@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Undecided - It is not yet clear if there is a plan to provide access
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The implementation protocol will be described in detail and clearly in the article, and the method of data collection will also be written.
When the data will become available and for how long
After printing the results, access will start
To whom data/document is available
Sports Physiology Specialists
Under which criteria data/document could be used
Under the conditions of the implementation of the protocol
From where data/document is obtainable
Mina Rigi rigimina74@gmail.com 09908483108
What processes are involved for a request to access data/document
After receiving the individual's request, the steps of implementing the sports protocol for the named person and with the informed consent of the applicant, blood sampling and testing and exercise procedures will be explained.
Comments