

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effects of resistance exercise and training with blood flow restriction on platelet-activating factors in patients with type 2 diabetes

Protocol summary

P-selectin, GpIIb / IIIa, Aggregation (ADP), fibrinogen, PT, PTT, hemoglobin PLT, PCT, MPV, and PDW

Study aim

The aim of this study was to investigate the effect of resistance exercise with restricted blood flow on platelet indices and platelet-activating factors in patients with type 2 diabetes.

Design

The statistical population includes patients with type 2 diabetes in the age range of 30 to 60 years in Kashan. The sample size is 15 people who perform an exercise with blood flow restriction in one stage and exercise without the restriction of blood flow in the next stage.

Settings and conduct

Resistance activity includes two sessions of resistance activity with and without restriction of blood flow. The subjects perform two training protocols in two sessions with an interval of 4 to 6 days. In the first session, after 20-30 minutes of rest, the subjects perform the resistance activity protocol of 3 sets of 6 repetitions of knee opening with 80% of a maximum repetition and the rest time between sets is 2 minutes without restriction of blood flow. Then, in the second session, after 20-30 minutes of rest, they perform the protocol of resistance activity with an intensity of 20% 1RM in three sets with 15 repetitions with 30 seconds of rest between each set with limited blood flow. The place for exercising is the university gym. Blood samples are taken before, immediately and 30 minutes after activity.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes should not have heart disease, including ischemic heart disease including MI, angina, arrhythmia, heart failure, valvular disease, and abnormal ECG.

Intervention groups

The intervention group performs two sessions of resistance activity with and without restriction of blood flow; Subjects perform two training protocols in two sessions with an interval of 4 to 6 days. The plan is executed as a cross over.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130901014540N2**

Registration date: **2021-01-04, 1399/10/15**

Registration timing: **retrospective**

Last update: **2021-01-04, 1399/10/15**

Update count: **0**

Registration date

2021-01-04, 1399/10/15

Registrant information

Name

Elahe Malekyian Fini

Name of organization / entity

Arak University

Country

Iran (Islamic Republic of)

Phone

+98 86 3277 7400

Email address

malekyian.e@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-08-26, 1399/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of resistance exercise and training with blood flow restriction on platelet-activating factors in patients with type 2 diabetes

Public title
The effects of resistance exercise and training with blood flow restriction on platelet-activating factors

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes should not have heart disease, including ischemic heart disease including MI, angina, arrhythmia, heart failure, valvular disease, and abnormal ECG. These patients should not take more than two types of medication at the same time and should not take insulin. Patients should not take antiplatelet drugs such as aspirin, NSAIDs, and Clopidogrel, have no history of regular exercise, have not performed resistance training in the last six months, and do not have joint disease.
Exclusion criteria:
History of specific infectious and immune diseases, smoking, consumption of alcoholic beverages, dietary supplements and anti-inflammatory drugs, muscle damage and damage to the knee and pelvic joints are the most important factors in the withdrawal of subjects in this research project. Patients with tissue or joint injuries following resistance training are excluded from the research plan.

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of the Medical Ethics Committee of the University of Kashan Medical Science

Street address

Qutb Ravandi Blvd. Holy Defense Bridge, University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

87159-81151

Approval date

2020-11-21, 1399/09/01

Ethics committee reference number

IR.KAUMS.REC.1399.035

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

platelet-activating factors

Timepoint

At the beginning of the study, immediately and 30 minutes after the activity

Method of measurement

Flow cytometry is used to measure P-selectin, GpIIb / IIIa.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Exercise group with limited blood flow: Perform light resistance exercise according to the stated protocol with limited blood flow.

Category

Diagnosis

2

Description

Control group: The group of sports activities without blood flow restriction that follows the defined protocol. The protocol is fully described in the abstract section

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

elahe malekyian

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Amirkabir St., Big Fin, Sadat neighborhood, Shafa alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

, Shahid Beheshti University

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

Full name of responsible person

elahe malekyian

Position

Ph.D. Student in Exercise Physiology

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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Other areas of specialty/work

Physiology

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

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Full name of responsible person

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Position

Ph.D. Student in Exercise Physiology

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

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City

kashan

Province

Isfahan

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

There is no more information

Study Protocol

No - There is not 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