# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

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

## Protocol summary


**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**

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


## 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**

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Elahe Malekyian Fini
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Arak University
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Iran (Islamic Republic of)
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**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**

Isfehan

**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**
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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

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## 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