

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

#### Protocol summary

##### Study aim

Comparison of the effectiveness of leg ergometry exercises with and without WB-EMS on blood glucose regulation in patients with type II diabetes in Imam Khomeini Hospital, Sari, in 2023

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 patients. SNOSE will be used for randomization.

##### Settings and conduct

Imam Khomeini Hospital, Sari, patients with type II diabetes will be included in the study according to the entry and exit criteria. In the clinical trial study, the SNOSE method will be used to hide (blinding) the random allocation.

##### Participants/Inclusion and exclusion criteria

Entry conditions: patients with type II diabetes, age 30 to 70 years, consent to participate in the study,  $7 < \text{HbA1C} < 10$ , no exogenous insulin use,  $\text{BMI} > 25$ , no heart pacemaker and defibrillator, no heart failure  
Symptomatic and uncontrolled exclusion conditions: lack of consent to participate in the study, withdrawal from participation in the study, absence of more than 2 sessions, presence of new diabetic foot ulcers or musculoskeletal defects, pregnant women, breastfeeding, presence of serious orthopedic, neurological or infectious disorders (joint Charcot, diabetic foot ulcer, amputation), uncontrolled seizures

##### Intervention groups

1) Patients receiving aerobic exercise by Leg Ergometry along with EMS 2) Patients receiving aerobic exercise by Leg Ergometry method without receiving EMS. The exercise that each patient receives is Leg Ergometry or stationary bicycle, which is performed for 30 minutes in the group without EMS and 20 minutes in the group with EMS. 3 sessions per week for 8 weeks of this training protocol will be done

##### Main outcome variables

Blood sugar level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210901052353N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **prospective**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

##### Registration date

2024-03-02, 1402/12/12

##### Registrant information

##### Name

seyed ali akbar mahmoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4440 5204

##### Email address

amahmoudi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-09, 1402/12/19

##### Expected recruitment end date

2024-04-19, 1403/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

#### Public title

Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with type II diabetes Age 30 to 70 years Consent to participate in the study HbA1C<10>7 No use of exogenous insulin BMI>25 Absence of pacemaker and defibrillator Not having symptomatic and uncontrolled heart failure Absence of psychiatric disorders No history of CVA, MI, Unstable angina in the last month Not having uncontrolled HTN

##### Exclusion criteria:

Lack of consent to participate in the study Withdrawal from participating in the study Absence of more than 2 sessions Presence of new diabetic foot ulcer or musculoskeletal defects pregnant lady breastfeeding Presence of serious orthopedic, neurological or infectious disorders (Charcot's joint, diabetic foot ulcer, amputation) Uncontrolled seizures Severe proliferative and non-proliferative diabetic retinopathy Change in dosage and type of oral medication

#### Age

From **30 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation by the method of variable blocks. In this study, the randomization method will be used to generate a random sequence using the block method and the Random allocation software. First, the informed consent form is registered by the patient in writing, and then the participants will be randomly assigned to each group.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

SNOSE method will be used to hide random allocation. This method is one of the common methods in hiding random allocation. In this method, a random sequence is first created using the mentioned software, then based

on the sample size of a number of envelopes with aluminum wrappers (in order to make the contents of the envelopes unclear), prepare and each of the random sequences created on It is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of the registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences, Imam Khomeini Hospital, Sari

###### Street address

Amir Mazandarani Boulevard, Imam Khomeini Hospital

###### City

Sari

###### Province

Mazandaran

###### Postal code

48166-33131

##### Approval date

2023-12-17, 1402/09/26

##### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1402.105

### 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

Blood sugar decreasing

##### Timepoint

At the beginning and before entering the study and at the end of week 8

**Method of measurement**

blood test

**Secondary outcomes**

**1**

**Description**

Oxygen consumption capacity or aerobic capacity per person

**Timepoint**

At the beginning and before entering the study and at the end of week 8

**Method of measurement**

Field test

**Intervention groups**

**1**

**Description**

Intervention group: Patients receiving aerobic exercise by Leg Ergometry along with EMS

**Category**

Treatment - Devices

**2**

**Description**

Control group: Patients receiving aerobic exercise by Leg Ergometry without receiving EMS

**Category**

Treatment - Devices

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital, Sari

**Full name of responsible person**

Seyyed Ali Akbar Mahmoudi

**Street address**

Imam Khomeini Hospital, Amir Mazandarani Boulevard, Sari

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amahmoudi@mazums.ac.ir

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<https://www.mazums.ac.ir>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saedi

**Street address**

Moalem Ave

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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**

Mazandaran University of Medical Sciences

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Akbar Mohammadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

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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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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