Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of eight weeks of combined aerobic-electrical stimulation and resistance-electrical stimulation exercises on the serum levels of IL-6, vWF, LDL, HDL and ADAMTS13 activity in men with ischemic stroke

Protocol summary

Study aim

Determining the effect of eight weeks of combined aerobic-electrical stimulation and resistance-electrical stimulation exercises on the serum levels of IL-6, vWF, LDL, HDL and ADAMTS13 activity in men with ischemic stroke.

Design

Due to the use of a human sample, this research is carried out in a semi-experimental way and in the form of a pre-test, post-test research design. The statistical population of this research is 40 men suffering from ischemic stroke from the clients of Tavana Physiotherapy Clinic in Hamedan, who were randomly divided into four groups of 10 people, including the combined exercise group (aerobic-electrical stimulation), the combined exercise group (resistance-electrical stimulation), the group of electrical stimulation alone and the control group are divided.

Settings and conduct

Before the start of training and 48 hours after the last training session, blood sampling will be done from all the subjects fasting by a laboratory expert. Then, after clotting and centrifugation, the serum sample will be separated and then in Hakim Hamedan laboratory at -80 degrees. Centigrade is kept until the levels of serum IL-6, vWF, LDL, HDL and ADAMTS13 activity are measured with an ELISA kit.

Participants/Inclusion and exclusion criteria

Entry requirements: Men with first or second ischemic stroke Age range 55-85 years Not taking any food supplements The patient has at least grade 3 muscle strength Able to walk at least 10 meters unaided or with assistive devices Non-entry conditions: Cardiovascular patients, hemorrhagic stroke

Intervention groups

Three intervention groups (aerobic-electrical stimulation, resistance-electrical stimulation and electrical stimulation only) and a control group that has no intervention until the end of the research.

Main outcome variables

The serum levels of IL-6, vWF, LDL, HDL and ADAMTS13 activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240922063118N1**
Registration date: **2024-11-21, 1403/09/01**
Registration timing: **retrospective**

Last update: **2024-11-21, 1403/09/01**
Update count: **0**

Registration date

2024-11-21, 1403/09/01

Registrant information

Name

Morteza Mostaghimi

Name of organization / entity

Boali University of Hamedan

Country

Iran (Islamic Republic of)

Phone

+98 81 3442 8158

Email address

saeiandbibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of combined aerobic-electrical stimulation and resistance-electrical stimulation exercises on the serum levels of IL-6, vWF, LDL, HDL and ADAMTS13 activity in men with ischemic stroke

Public title

The effect of exercise with electrical stimulation on inflammation and hemostasis system in stroke patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Men with first or second ischemic stroke with right or left hemiparesis Age 55-85 years Not taking any food supplements for 3 months before the research The patient has at least grade 3 muscle strength from manual muscle test Able to walk at least 10 meters without assistance or with assistive devices

Exclusion criteria:

Cardiovascular discomfort The patient's inability to perform physical activity Hemorrhagic stroke

Age

From **55 years** old to **85 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling framework was prepared by preparing a list including all subjects, which were numbered from 1 to 40. Then random numbers from 1 to 40 were selected using the Random Number Generator. Each number was placed in aerobic, resistance, electrical stimulation and control groups, which were finally divided into four groups of 10 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

All the subjects were informed about the objectives of the research from the beginning, but they were not given information about the research and intervention groups. They only did the exercises of each session under the supervision of the researcher.objectives.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Boali Sina University, Hamedan

Street address

No. 12, Fedayian Islam Alley, Azadegan Blvd.

City

Hamedan

Province

Hamadan

Postal code

6518834386

Approval date

2024-08-28, 1403/06/07

Ethics committee reference number

IR.BASU.REC.1403.014

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

von Willebrand factor

Timepoint

Before the start of the exercise and after the end of the exercise

Method of measurement

ELISA kit

2

Description

ADAMTS13

Timepoint

Before the start of the exercise and after the end of the exercise

Method of measurement

ELISA kit

3

Description
Interleukin 6
Timepoint
Before the start of the exercise and after the end of the exercise
Method of measurement
ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aerobic-Electrical stimulation
Category
Diagnosis

2

Description
Intervention group: Resistance-Electrical stimulation
Category
Diagnosis

3

Description
Intervention group: Electrical stimulation
Category
Diagnosis

4

Description
Control group: Control
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic, Hamadan
Full name of responsible person
Dr. Mehrdakht Mazdeh
Street address
Imam Khomeini Clinic, Mirzadeh Eshghi Street, Shariati Square
City
Hamedan
Province
Hamadan
Postal code
6518834385
Phone
+98 81 3442 5668
Email
saeiandbibak@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Assistant of Bu-Ali Sina University
Full name of responsible person
Dr. Arash Ghorbani Chaghamarani
Street address
Research and Technology Office of an assistant, Bu-Ali Sina University, Martyr Mostafa Ahmadi Roshan Street, Hamedan
City
Hamedan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۶۹۵
Phone
+98 81 3140 5555
Email
a.ghorbani@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Assistant of Bu-Ali Sina 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
Boali Sina University
Full name of responsible person
Morteza Mostaghimi
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiology
Street address
No. 12, Fedayian Islam Alley, Azadegan Blvd.
City

Hamedan

Province
Hamadan

Postal code
6518834386

Phone
+98 81 3442 8158

Email
saeiandbibak@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bu Ali Sina University

Full name of responsible person
Morteza Mostaghimi

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiology

Street address
No. 12, Fedayian Islam Alley, Azadegan Blvd.

City
Hamedan

Province
Hamadan

Postal code
6518834386

Phone
+98 81 3442 8158

Email
Saeiandbibak@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Bu Ali Sina University

Full name of responsible person
Morteza Mostaghimi

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiology

Street address
No. 12, Fedayian Islam Alley, Azadegan Blvd.

City
Hamedan

Province
Hamadan

Postal code
6518834386

Phone
+98 81 3442 8158

Email
Saeiandbibak@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
Yes - There is 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
Only non-confidential documents and items will be shared

When the data will become available and for how long
1 year after the results are published

To whom data/document is available
Academic researchers and neurologists

Under which criteria data/document could be used
Only for the scientific and therapeutic use of researchers and specialists in the field of treatment

From where data/document is obtainable
Faculty of Physical Education and Sports Sciences, Boali Sina University, Hamedan

What processes are involved for a request to access data/document
Email to the author responsible for the published article

Comments