

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of alternative or continuous exercise on brain biomarkers and neurological scores in patients with ischemic stroke

Protocol summary

Study aim

Comparison of the effect of alternative or continuous exercise on brain biomarkers and neurological scores in patients with ischemic stroke

Design

Our subjects will be selected after being qualified to meet the preliminary conditions, among patients who refer to Loghman Hospital Emergency with stroke diagnosis. After ethical approval and filling out consent and general specification forms, by available sampling method, 45 subjects in the range of 45 to 65 years old, will be divided into two experimental groups plus a control group of 15 members without randomization. On the first and thirtieth day, five CC blood specimen will be taken from patients while all of them are under same medication and diet.

Settings and conduct

HIT group : 30 s × 4-6 repeats, 4.5 min rest (3 sessions per week) 70- 80 % of VO₂ peak Training intensity (workload) by using a bicycle rehabilitation facility.
Endurance group: 40-60 min cycling (5 sessions per week) 65% of V₂O₂ peak Training intensity (workload)

Participants/Inclusion and exclusion criteria

People with a history of using cannabis and marijuana, coagulation problems, heart failure, cancer, Advanced renal and liver failure, uncontrolled blood pressure, respiratory failure, consume supplements, mental disorders, vascular aneurysms, history of previous stroke and hemorrhagic, transient ischemic attacks, Open wounds and trauma to the head area will be excluded from the group; The entry of an ischemic stroke, aged between 45 and 65 years old, has one of the factors that causes stroke, the ability to exercise, the same drug protocol, Not having skeletal dysfunction

Intervention groups

Experimental group HIT : 4 weeks Continuing training for 5 times a week +physiotherapy
Experimental group Endurance : 4 weeks periodic exercise for three times a week + physiotherapy
Control group: only Physiotherapy

Main outcome variables

biomarkers and neurological scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100518003943N1**

Registration date: **2019-10-08, 1398/07/16**

Registration timing: **retrospective**

Last update: **2019-10-08, 1398/07/16**

Update count: **0**

Registration date

2019-10-08, 1398/07/16

Registrant information

Name

Mahshid Kadkhodaei Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6688 7472

Email address

mahshid_kadkhodaei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of alternative or continuous exercise on brain biomarkers and neurological scores in patients with ischemic stroke

Public title

Effects of the Type of Exercise in Brain Bio markers

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic stroke In the age group between 55 and 60 years Has one of the factors that causes stroke Ability to exercise The same drug protocol lack of skeletal dysfunction

Exclusion criteria:

Hemorrhagic stroke and TIA heart failure advanced renal failure and heart failure aneurysm, use of tobacco, alcohol having coagulation problems using supplements and vitamin C advanced liver failure history of previous stroke trauma sclerosis and rheumatism cancer Consume up to 5 cigarettes per day

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Ischemic stroke

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Arabi Ave, Bldg No.2 SBUMS, 7th Floor, Velenjak.

Tehran Province, Tehran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1018

Health conditions studied

1

Description of health condition studied

Occlusion and stenosis of middle cerebral artery

ICD-10 code

I66

ICD-10 code description

Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction

Primary outcomes

1

Description

Changes in serum levels of vascular endothelial growth factor

Timepoint

Before starting the study and 4 weeks later

Method of measurement

Sample Of Blood And Human Eliza kit

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before the intervention and 4 weeks after the workout

Method of measurement

Mini-international neuro psychiatric interview

Intervention groups

1

Description

First intervention group: 15 participants of the training group after familiarity with the workout environment, using the rehabilitation bike, HIT aerobic training for 3 seconds, 4-6 repetitions with high intensity and 4 minutes resting to 70-80% of maximum oxygen Consume, then cool down for 3 minutes with stretching exercises, 3 times a week, with a constant physiotherapy program for 28 days.

Category

Rehabilitation

2

Description

Second Intervention group : 15 participants after familiarization with the workout environment, using a rehab exercise bike for a continuous training period of 40 to 60 minutes with a low intensity of 60 to 65% of the maximum oxygen consumed below the maximum and based on the level of readiness level Physical activity is performed, then cool for 2 minutes, 5 days a week, with a constant physical therapy program for 28 days.

Category

Rehabilitation

3

Description

Control group: Only do a fixed physiotherapy program within 28 days.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

kadkhodaei khalafi Mahshid

Street address

Makhsus, Makhsus St, Qazvin St.Tehran Province, Tehran, Tehran,Iran .

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1334-631151

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+98 21 5102 5000

Email

mahshid_kadkhodaei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

kadkhodaei khalafi Mahshid

Street address

N ., Makhsus St., Qazvin St., kamali St..Tehran Province, Loghman Hakim

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Province

Tehran

Postal code

1334-631151

Phone

+98 21 5102 5000

Email

mahshid_kadkhodaei@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

40

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

Islamic Azad University

Full name of responsible person

Kadkhodaei Khalafi Mahshid

Position

Sport Physiology PhD Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

N 22., 2th floors., Ghrah Pasha Ally., Foad Mossavi St., Azarbygan St., Tehran Town

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kadkhodaei.m1350@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kadkhodaei Khalafi Mahshid

Position

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

A portion of the data, such as the original outcome information

When the data will become available and for how long

Get started 6 months after printing results

To whom data/document is available

Academic and scientific institutions and the public

Under which criteria data/document could be used

Access to final results through article download

From where data/document is obtainable

E-mail

What processes are involved for a request to access data/document

A week after the request

Comments