

# 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 VO<sub>2</sub> peak Training intensity (workload) by using a bicycle rehabilitation facility.  
Endurance group: 40-60 min cycling (5 sessions per week) 65% of V<sub>2</sub> O<sub>2</sub> 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 .

##### City

Tehran

##### Province

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##### Postal code

1334-631151

##### Phone

+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

##### City

Tehran

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1345916174

##### Phone

+98 21 6688 7472

##### Email

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

Sport Physiology PhD Student

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Email**

mahshid\_kadkhodaei@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**

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**