Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 V˙O2 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 scienece
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 Haspital
Full name of responsible person
khadkhodaei khalafi Mahshid
Street address
Makhsus, Makhsus St, Qazvin St.Tehran Province, Tehran, Tehran,Iran .
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mahshid_kadkhodaei@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
khadkhodaei 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
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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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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