

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison of Acute stress persistence in ischemic stroke patients with healthy patients

Protocol summary

Study aim

Comparison of acute stress persistence in patients with chronic ischemic stroke with healthy individuals

Design

this study will be conducted in the pilot phase because without same study, with 10 healthy individuals in the control group and 10 patients with chronic ischemic stroke. Patients were randomly selected from the list of stroke patients and healthy subjects were selected from relatives of the same patients which were homogenized in terms of age and BMI.

Settings and conduct

eligible patients are called to the hospital and After arriving and obtaining written informed consent ,they should fill the questionnaires on individual characteristics and Spillberger's Anxiety Inventory. Then a saliva sample is taken and the ECG is recorded. Then the person enters the TSST protocol in order to become mildly stressed. After the protocol, the saliva will be obtained immediately and After twenty minutes and forty minutes, salivary sample and ECG tests will be repeated. Finally, the blood sample is taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. men with 18 to 70 years old
2.occurrence of ischemic stroke in 6 months to 3 years before the participation which approved by CT scan or MRI 3. Modified Ranking Scale ≤ 3 in stroke patients 4. Absence of systemic disorders like Diabetes, autoimmune, cardiovascular, neurological or psychiatric disorders 5.No smoking at least one day before the test 6. No severe exercise at least one month before the test
exclusion: no continue participation, unstable condition for general health

Intervention groups

intervention group : patients with chronic ischemic stroke
control group: healthy individuals

Main outcome variables

1. Spillberger Anxiety Test Score 2. Salivary Cortisol levels before testing 3. Salivary Cortisol levels after the

test 4. CD Heart Rate Variability 5. The amount of glutathione peroxide 6. The amount of vitamin E

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037666N1**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **retrospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Boshra Hatef

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3225 3495

Email address

boshrahatef@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-18, 1396/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of Acute stress persistence in ischemic stroke patients with healthy patients

Public title

Acute stress persistence in ischemic stroke patients

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

The first inclusion criteria is the incidence of ischemic stroke should be 6 months to 3 years before the study, which approved by CT scan or MRI The Modified Ranking Scale for chronic stroke patients should be ≤ 3 The participants should not be disordered with systemic disorders like Diabetes, autoimmune disorders, cardiovascular disorders and neurological or psychiatric disorders. The participants should not have cigarette smoking at least one day before the study The participants should not have severe exercise at least one month before the study

Exclusion criteria:

Failure to cooperate in completing test procedures

Age

From **18 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we use Random number table for randomizing

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Baghiatallah University of Medical Sciences

Street address

mollasadra Ave, Vanak sq, Tehran

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Postal code

881435916471

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.BMSU.REC.1396.4

Health conditions studied**1****Description of health condition studied**

chronic ischemic stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Salivary cortisol levels before and after intervention

Timepoint

Salivary cortisol levels before intervention, immediately after intervention, twenty minutes after intervention and forty minutes after intervention

Method of measurement

The concentration of cortisol in the saliva samples measure in the laboratory by the salivary cortisol assay kit.

Secondary outcomes**1****Description**

linear and non-linear features of heart rate variation

Timepoint

linear and non-linear indicators of heart rate fluctuations as a secondary outcome, can be measured immediately before the TSST intervention, during the TSST protocol, twenty minutes after the end of the protocol, and forty minutes after the end of the protocol.

Method of measurement

ECG instrument

Intervention groups**1****Description**

Intervention group: People with chronic stroke. Type of intervention: Stress which is generated by the TSST

protocol. During this protocol, the person is initially interviewed for 2 minutes by a doctor, and then for 13 minutes, math questions are asked in the form of a subtraction of certain numbers, so that he becomes significantly stressed.

Category

Early detection

2

Description

Control group: age- matched health participants with patients. Type of intervention: Stress which is generated by the TSST protocol. During this protocol, the person is initially interviewed for 2 minutes by a doctor, and then for 13 minutes, math questions are asked in the form of a subtraction of certain numbers, so that he becomes significantly stressed.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuroscience Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran.

Full name of responsible person

Omid Mirzaee

Street address

mollasadra Ave, Vanak Sq, Teehran, Iran

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boshrahatef@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

boshra hatef

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Boshra Hatef

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

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

Title and more details about the data/document

all data are shareable after recognizing the individuals

When the data will become available and for how long

Start the access period from 1400

To whom data/document is available

Only researchers working in universities

Under which criteria data/document could be used

No more information

From where data/document is obtainable

corresponding author

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

Sending an email to the corresponding author

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Bagheiatallah University of Medical Sciences

Full name of responsible person

Omid Mirzaee

Position

general physician

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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